Petition

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No._____

IN THE

SUPREME COURT OF THE UNITED STATES

October Term, 1981

GLYNN RICHARD DAVIS,
Petitioner,

vs.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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QUESTIONS PRESENTED

1. Where the federal government has unique knowledge of potential risks to the health of citizens who participate in government programs, what is the nature and scope of the government's duty to inform the public of those risks?

2. Whether accrual of a cause of action within the meaning of 28 U.S.C. § 2401(b) is deferred where plaintiff's failure to discover the cause of his injury within two years of incurring it results from the government's acts in concealing information essential to his cause of action?

3. Whether the concealment doctrine tolls the statute of limitations, 28 U.S.C. § 2401(b), where plaintiff's failure to sue within two years of incurring an injury results solely from the government's misrepresentations to the public and failure to produce documents sought by a subpoena served on the government?

4. Whether the principles of equity applicable to statutes of limitations preclude the government from asserting a limitations defense where the government has concealed from the plaintiff information necessary to predicate his claim against the government?

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
OPINIONS BELOW.	1
JURISDICTION.	1
STATUTES AND REGULATIONS.	2
STATEMENT OF THE CASE	3
JURISDICTION IN THE COURT OF FIRST INSTANCE	17
REASONS FOR GRANTING THE WRIT . . .	18
I. In the context of the statute of limitations to the Federal Tort Claims Act, this case presents an important question of federal law concerning the nature and scope of the government's duty to inform the public of risks associated with government programs which encourage mass citizen participation.	49
II. The decision below conflicts with this Court's decision of United States v. Kubrick, 100 S.Ct. 352 (1979).	25
III. The decision below conflicts with settled federal law which tolls statutes of limitations where the government conceals from a plaintiff evidence which is crucial to his cause of action.	35

CONCLUSION. 42

APPENDICES
Appendix A. A-1
Appendix B. A-19
Appendix C. A-21
Appendix D. A-22
Appendix E. A-25
Appendix F. A-27
Appendix G. A-51
Appendix H. A-56
Appendix I. A-59
Appendix J. A-62
Appendix K. A-82
Appendix L. A-98
Appendix M. A-113
Appendix N. A-124
Appendix O. A-129

TABLE OF AUTHORITIES

	Pages
Cases:	
Camire v. United States, 535 F.2d 749 (2d Cir. 1976).	34
Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 123 (9th Cir. 1968) .	4
Gicas v. United States, 508 F.Supp. 217 (E.D.Wis. 1981)	23
United States v. Kubrick, 100 S.Ct. 352 (1979).	25, 42
Marshall v. Kimberly-Clark Corp., 625 F.2d 1300 (5th Cir. 1980) . . .	34
Public Service of New Mexico v. General Electric Co., 315 F.2d 306 (10th Cir.)	36
Rahn v. United States, 222 F.Supp 775 (S.D.Ga. 1961).	24, 36
Spevack v. United States, 390 F.2d 977 (Ct.Cl. 1968).	37
Toal v. United States, 438 F.2d 222 (2d Cir. 1971)	38

Pages

Statutes:

Federal Tort Claims Act, 28 U.S.C. § 1346(b) 17

Federal Tort Claims Act, 28 U.S.C. § 2401(b) 18, 30

National Swine Flu Act of 1976, 42 U.S.C. § 247(b). 22

Regulations:

42 C.F.R. § 73.114(b)(1)(iii) . . . 6, 7

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OPINIONS BELOW

The Opinion of the Ninth Circuit Court of Appeals was entered on April 20, 1981, and has been reported at 642 F.2d 328 (9th Cir. 1981). (Appendix A.) The district court's order on defendant's motion for Summary Judgment was entered on March 29, 1977 (Appendix D), and is

not reported. The district court's judgment granting the government summary judgment was entered on the same day. (Appendix E.)

JURISDICTION

The judgment of the Ninth Circuit Court of Appeals was entered on June 22, 1981. (Appendix C.) The order of the Ninth Circuit denying a timely petition for rehearing and rejecting the suggestion for rehearing en banc was entered on May 28, 1981. (Appendix B.)

The jurisdiction of this Court is invoked under Title 28, United States Code, Section 1254(1).

STATUTES AND REGULATIONS

The federal tort claims act, 28 U.S.C. § 2401(b) which provides:

> A tort claim against the United States shall be forever barred unless it is presented in writing to the appropriate Federal agency within two years after such claim accrues or unless action is begun within six months after the date of mailing, by certified or registered mail, of notice of final denial

of the claim by the agency to which it was presented.

The Federal Tort Claims Act, 28 U.S.C. § 1346(b) which provides:

> Subject to the provisions of chapter 171 of this title, the district courts, together with the United States District Court for the District of the Canal Zone and the District Court of the Virgin Islands, shall have exclusive jurisdiction of the civil actions on claims against the United States, for money damages, accruing on and after January 1, 1945, for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

42 C.F.R. 73.114(b)(1)(iii). (Appendix O.)

STATEMENT OF THE CASE

Participating in the federal government's campaign to eliminate paralytic poliomyelitis, petitioner Davis took Type

III oral polio vaccine at a mass immunization clinic conducted in West Yellowstone, Montana in March, 1963. Within four weeks of ingesting the vaccine he was paralyzed from the waist down and has continuously remained in that condition. (Appendix F, p. A-28.)

The mass immunization plan was conceived by an advisory committee established in 1960 by the Surgeon General. The committee formulated a plan to create mass immunization centers throughout the country, and in March, 1962, the Surgeon General, acting on behalf of the Public Health Service, issued recommendations for the use of the Sabin oral vaccine. As part of the program, representatives of the Public Health Service held meetings with local public health officials and medical personnel in communities throughout the United States. Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 123 (9th Cir. 1968).

The vaccine involved was Sabin oral vaccine which consisted of three separate types: Types I, II, and III. Each type was designed to immunize the person inoculated from contracting polio from a corresponding type of polio virus. Id. at 122. Unlike the predecessor Salk vaccine, the Sabin vaccine utilized live virus.

In addition to creating the immunization clinics, the federal government controlled the licensing and testing of the vaccine through the Division of Biologics Standards (DBS) of the National Institutes of Health, an arm of the United States Department of Health, Education and Welfare. The government licensed three companies to manufacture the vaccine, including Wyeth Laboratories, Inc., which produced Lot 35, from which Davis was vaccinated.[1]

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[1]In 1964 Davis sued Wyeth on the basis of diversity jurisdiction. The trial court entered judgment against him, and the Ninth Circuit reversed. Davis v. Wyeth, supra. That case was settled without a second trial.

Government regulations required each manufacturer, after producing a lot, to perform prescribed tests on it and submit the test results, together with a sample from the lot, to the DBS, where the government performed additional tests to determine its safety, potency, and purity. If the lot satisfied government standards, the DBS authorized its dissemination to the public.

Dr. Ruth Kirschstein was the DBS pathologist responsible for supervising the government testing. Her deposition was taken on October 21-22, 1965 in the Davis v. Wyeth litigation, and on May 12, 1975, in the instant litigation. (The former deposition is hereinafter referred to as Kirschstein Dep. I and the latter, as Kirschstein Dep. II.)

The critical test which DBS performed on each lot was the neurovirulence test, in which a sample from a vaccine lot was injected into the brain or spinal

column of a test animal. After destruction of the animal following an observation period, a section of tissue was removed from the brain or spine and subjected to a histologic examination to determine the number and severity of lesions, or deviations from the norm. Lesions were graded on an increasing scale of severity from 1 to 4. (Kirschstein Dep. I, p. 103.) The occurrence of lesions in the test lot was then compared to a reference strain of vaccine maintained by the DBS pursuant to 42 C.F.R. § 73.114(b)(1) (iii), which provided that a test lot was satisfactory for manufacture only if "a comparative analysis of the test results demonstrates that the neurovirulence of the test virus pool does not exceed that of the NIH Reference Attenuated Polio Virus."

Wyeth's Lot 35 was subjected to two tests. Prior to Dr. Kirschstein's deposition in October, 1965, she was served

with a subpoena directing the DBS to produce all its records pertaining to Lot 35. Yet at this deposition she failed to produce the results of a second neurovirulence test which had been performed on the lot. (Kirschstein Dep. II, pp. 21-23, 30, 33-34.) The results of the second test, included as Appendix I hereto, contain the critical evidence that Lot 35 exceeded the neurovirulence of the NIH reference strain of virus and therefore violated the applicable regulation, so that the lot never should have been released. (Appendix G.) Indeed, the results of this second test on Lot 35 showed the first grade 4 lesion recorded by the DBS testing (Appendix G), which was the most severe on the DBS range of severity.

Because the government failed to produce the results of the second test at Dr. Kirschstein's deposition in 1965, it was only fortuitously that Davis was informed of these facts in 1973 by an

attorney representing another person who had contracted polio from taking the vaccine. (Appendix F, p. A-31.) When Davis obtained this crucial information, he promptly filed suit against the government alleging negligent release of Lot 35. (Appendix F, pp. A-31-32.)

He had earlier sued Wyeth on the theory of strict liability for failure to warn of the risk that a person could contract polio from ingesting the Sabin vaccine. In that case, Davis had no evidence of any defect in Lot 35 because of the government's concealment of the results of the second test, and was able to offer only epidemiological proof that the vaccine had caused his disease. (Appendix F, p. A-42.) Indeed, the Ninth Circuit Court of Appeals, which ruled in Davis's favor in the Wyeth litigation, believed that the Lot satisfied government standards. Davis v. Wyeth, supra, 399 F.2d at 123. Of course, the court like

Davis had access to only the first test produced at Dr. Kirschstein's deposition in 1965.

The record is replete with evidence that Davis aggressively sought to determine the cause of his paralysis, yet he was repeatedly told that it was impossible to prove that a particular case of polio was caused by the vaccine and that cases which showed a possible epidemiological link with the vaccine were not associated with any particular lots. (Appendix F.)

Davis's affidavit attached as Appendix F describes in detail his efforts to learn the cause of his injury. Only three months after contracting the disease he began to write letters to epidemiologists and other scientists and to review literature on polio contained both in medical journals and government publications. (Appendix F.) He wrote to the

Director of the Food and Drug Administration and the Public Health Service. He corresponded with the Administrator of National Health and Welfare in Canada and in the summer of 1964, wrote to Dr. Sabin himself, who responded that there was absolutely no way that he could have contracted polio from the vaccine. (Appendix F, pp. A-38-39.) In July, 1964, Davis's attorneys consulted with Dr. Salk, developer of the predecessor vaccine, and he too, was unable to state that there was any association of particular vaccine lots with inducement of the disease. (Appendix F, p. A-39.) In a letter to the Washington State Department of Health which Davis wrote in October, 1963, he stated that not one of nearly 20 doctors who had examined him would acknowledge that his paralysis could have been caused by the vaccine. (Appendix A, p. A-16.)

Davis's conscientious review of the literature proved no more fruitful. A June, 1963 article by Dr. Gelfand, Chief of the Enterovirus Unit of the Communicable Disease Center, stated that "it remained impossible to decide whether or not an individual case had been caused by the oral vaccine. . . ." (Emphasis added.) (Appendix M, p. A-121.) The same article stated that "[N]o evidence has been adduced to show that this vaccine, composed of these strains, had ever caused the disease it was designed to prevent." (Emphasis added.) (Appendix F, p. A-35.)

In addition to medical journals, Davis, beginning only a few months after the onset of his disease, thoroughly read the documents which the government distributed concerning the issue of possible association of polio with ingestion of the oral vaccine.

Sometime in 1962 the Surgeon General, Dr. Luther Terry, formed a Special Oral Poliomyelitis Vaccine Advisory Committee (Committee) comprised of some of the world's foremost experts on epidemiology and virology. The Committee included scientists working both within and without the federal government. Some of the members were Dr. Ernest Ager, an epidemiologist employed by the Washington Department of Health; Dr. Albert Sabin, the creator of the oral vaccine; and Dr. Roderick Murray, director of the DBS. (Appendix L, pp. A-106-108.)

The findings of the Committee's meetings, held from August, 1962 through July, 1964, were published in the Committee's reports, as well as reports and press releases issued by the Surgeon General. The meeting of September 15, 1962 was described in the September 20, 1962 technical report authored by the Surgeon General. (Appendix J.) This was

one of several reports that the Committee published after September 3, 1962, the date of completion of the second neurovirulence test on Lot 35.

The September 20 report related that the Committee had reviewed data concerning the occurrence of polio cases after administration of the oral vaccine and had examined those cases which it considered not inconsistent with a vaccine relationship. The report noted that the vaccine administered to those cases was from several lots not produced by a single manufacturer. The Committee was able to conclude only that the reported cases were "clinically consistent with paralytic poliomyelitis and with laboratory findings which could not exclude a possible relationship to the administration of oral vaccine." Thus, this Committee, composed of some of the world's most eminent experts on polio, could do no more than acknowledge its inability to exclude a

possible relationship between ingestion of vaccine and contraction of polio.

In its next report, issued in December, 1962, it firmly stated that it "does not consider that an individual case can be proved to be caused by the vaccine and no laboratory test has thus far provided a definitive answer." (Emphasis added.) (Appendix K, p. A-87.) The public was in effect being informed that there existed no possible cause of action against a drug manufacturer or any other party predicated on a defect in a particular lot of vaccine.

With respect to those cases considered to be "compatible" with the possibility of having been induced by the vaccine (Appendix K, p. A-87), the prevailing scientific thinking was that the vaccine relationship to disease was a general property of the vaccine rather than defects in manufacture. This view was re-emphasized in a September, 1964

press release of the Surgeon General. (Appendix L, p. A-102.)

On September 30, 1964, the Surgeon General released a document listing reported cases of polio which the Committee considered compatible with the possibility of having been induced by the vaccine. Davis's case is contained in that list. (Appendix L, p. A-111.) Davis read this report almost immediately upon its publication.

Not until he learned the results of the second test did Davis have any reason to believe that the cause of his paralysis was a defect in Lot 35. The results of this second test constituted the sole evidence that the cause of his disease was a peculiar property of Lot 35 rather than a generic characteristic of Type III vaccine. Prior to learning of the second test, he had relied on the government's representations that it was impossible to

prove that the disease could be caused by a specific lot of vaccine.

In none of its reports did the Committee ever state that any lot had failed to meet government standards. Indeed, the affidavit of Ernest Ager, a Committee member, reveals that Dr. Murray represented to the Committee at its July, 1964 meeting, that all lots of Type III vaccine which had been tested up to that time had satisfied government standards. (Appendix H, p. A-56.) Dr. Murray's representation was made despite the results of the second neurovirulence test on Lot 35, conducted more than a year and a half earlier, which showed that that lot violated the applicable regulation.

JURISDICTION IN THE COURT OF FIRST INSTANCE

The basis for federal jurisdiction in the district court was the Federal Tort Claims Act, 28 U.S.C. § 1346(b).

REASONS FOR GRANTING THE WRIT

I.

IN THE CONTEXT OF THE STATUTE OF LIMITATIONS TO THE FEDERAL TORT CLAIMS ACT, THIS CASE PRESENTS AN IMPORTANT QUESTION OF FEDERAL LAW CONCERNING THE NATURE AND SCOPE OF THE GOVERNMENT'S DUTY TO INFORM THE PUBLIC OF RISKS ASSOCIATED WITH GOVERNMENT PROGRAMS WHICH ENCOURAGE MASS CITIZEN PARTICIPATION.

This case presents very important questions of construction of 28 U.S.C. § 2401(b) in the context of far-reaching government programs designed to affect the lives of millions of American citizens. The effect of the polio vaccine program on some citizens, like petitioner, was permanent paralysis. The government knew as early as 1962 that some cases of polio were associated with ingestion of the Sabin vaccine, yet through the Surgeon General and his advisory Committee, the government repeatedly informed the public that there was no possible way to prove that the vaccine caused a particular

case of polio and that there was no demonstrable association of a case of polio with any particular lot.

The Surgeon General and the Committee made these representations despite the existence of evidence, as early as September, 1962, that at least one lot of vaccine, Lot 35, exceeded the government's permissible level of neurovirulence and thus did not meet the government's safety criteria. During all its meetings between 1962 and 1964, the Committee knew that the DBS's purpose in conducting neurovirulence tests on each lot of vaccine was to determine whether it exceeded the neurovirulence of the DBS's reference strain of vaccine, i.e., to ascertain whether or not a particular lot was safe for public use. In Davis's case the government's misrepresentations were compounded by concealment of the results of the second DBS test on Lot 35,

which constitutes the very heart of his claim.

This is the setting in which § 2401(b) must be construed in this case. The government created and administered a nationwide program designed to impact the lives of virtually all American citizens in the most important conceivable matter --life itself. The government initiated the campaign, supervised establishment of immunization clinics, and strictly regulated the testing and licensing of vaccine.

The polio immunization program is an example of the extensive role of guardian or watchdog for the public which the government has increasingly assumed in recent decades. The government's undertaking such an active involvement in the lives of its citizens raises the vital question of the corresponding duties the government incurs to provide citizens with accurate information about government programs, including full disclosure

of potential risks associated with participation in them.

In the polio immunization program, the government's knowledge of the field was vastly superior to that of the average citizen. The government had almost exclusive control over the resources and personnel necessary to carry out the project. Because of its superior knowledge and control, the government was in effect the public's guardian and only safeguard in this highly technical area. The government occupied a position of trust and enormous influence vis-a-vis the public. In its role of guardian the government assumed the duty to all members of the public to deal with them at arm's length and to imform them fully of all aspects of that program which could potentially affect their lives.

The evidence in this case is overwhelming that the government did not discharge its duty. The Surgeon General's

reports represented to Davis and others in his position that there was no way to prove that the vaccine caused a particular case of polio. Further, by failing to produce the results of the critical test on Lot 35, the DBS concealed from him, whether through negligence or otherwise, the crucial piece of evidence in his case which established that his polio was indeed caused by the vaccine.

As the government continues to play a pervasive role in the regulation of myriad technical matters affecting the public health, it is very likely that there will arise other cases which present similar issues involving construction of § 2401(b). One illustration of the type of program likely to produce limitations issues similar to this one is the swine flu immunization program created by the National Swine Flu Act of 1976, 42 U.S.C. § 247(b). The federal government's objective under the Act was to

inoculate the entire adult population of the United States against threat of a swine flu epidemic. It was the largest immunization program in the nation's history, and over 45 million Americans were vaccinated. Gicas v. United States, 508 F.Supp. 217 (E.D.Wis. 1981).[2]

In executing programs like the polio immunization campaign in which the public justifiably places great reliance on the government's expertise and good faith, the government should not be permitted to make misrepresentations to the public, conceal vital information and then employ its misrepresentations and concealments by invoking the statute of limitations to

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[2]Under the Act the United States assumed liability for damages sustained as a result of the inoculation. One reason that the government assumed this responsibility was the collapse of the commercial liability insurance market for vaccine manufacturers occasioned by petitioner's earlier case of Davis v. Wyeth, supra. Gicas, supra, 508 F.Supp. at 218-219. It is ironic that Davis remains uncompensated by the government for injuries he incurred more than 18 years ago.

deprive a citizen of a legitimate claim under the Federal Tort Claims Act. To sanction such a result would enable a defendant to profit from his own wrong and thus violate the most fundamental of equitable precepts. Rahn v. United States, 222 F.Supp. 775 (S.D.Ga. 1963).

Statutes of limitation themselves are an equitable device designed to insulate potential defendants from dilatory tactics. Conversely, the discovery rule used in the construction of § 2401(b) and the concealment doctrine are equitable concepts intended to protect plaintiffs from harsh application of statutes of limitations in circumstances where plaintiffs, despite the exercise of reasonable diligence, cannot discover causes of action because of the acts of prospective defendants.

The discovery rule and the concealment doctrine both apply to this case.

Those rules must be analyzed in the context of the government's duty to inform the public when the government undertakes to create and police a national plan affecting the public health.

II.

THE DECISION BELOW CONFLICTS WITH THIS COURT'S DECISION OF UNITED STATES V. KUBRICK, 100 S.CT. 352 (1979).

The majority of the court below correctly observed that while the present case does not involve medical malpractice, it is in many ways similar to such an action, and it is therefore here appropriate to apply the "discovery rule" under which a cause of action does not accrue until the plaintiff discovers, or in the exercise of reasonable diligence should have discovered, both his injury and its cause. (Appendix A, pp. A-5-6.) As Judge Tang perceived in his dissent, while the majority may have correctly stated the rule of Kubrick, supra, it

clearly erred in its purported application of Kubrick to the facts of this case.

As Judge Tang observed, there are vital distinctions between this case and Kubrick which require reversal of the decision below affirming the summary judgment. The record contains undisputed facts which as a matter of law establish that Davis's cause of action did not accrue until 1973 when he learned of the results of the second neurovirulence test on Lot 35. At a bare minimum this evidence created a genuine issue of material fact of the point in time at which he knew (1) of his injury and (2) its cause.

These are the key differences between the facts of Kubrick and this case: (1) there was no evidence in Kubrick that the government had failed to disclose to the plaintiff any documents relevant to his case; (2) long before two years had elapsed from the occurrence of his injury,

Kubrick had been informed by a physician that it was "highly possible" that his deafness had been caused by administration of the drug neomycin, whereas Davis was on numerous occasions informed by various sources that it was impossible to prove that his polio was caused by the vaccine and that there was no known association of polio cases with particular lots of vaccine; (3) unlike Davis, Kubrick had available to him alternative sources of information concerning the cause of his injury; (4) Kubrick failed to make diligent inquiry concerning the cause of his injury, whereas Davis doggedly pursued the truth about his paralysis; and (5) in Kubrick there was no showing that the government had made any public representations concerning the drug neomycin.

Nine months after the surgery in which he was treated with neomycin Kubrick was informed by a doctor that it was "highly possible" that his hearing loss

resulted from administration of this drug. It was common knowledge in the medical community at that time that this application of neomycin was improper because it could cause precisely this consequence.

By contrast, Davis did not learn until 1973 of the cause of his injury--a defect in Lot 35. As opposed to Kubrick's being informed by a physician of a high possibility that neomycin caused his deafness, at most Davis may have suspected that the vaccine caused his disease. Knowledge of cause and a mere suspicion cannot be equated for purposes of applying Kubrick. Most important, the government never revealed to Davis the critical evidence on causation--the second test on Lot 35.

As Judge Tang stated, far from suggesting a high possibility that his paralysis and the vaccine were causally linked, numerous reputed authorities informed

Davis that the vaccine could not be proved to cause the disease. In 1964 Dr. Sabin himself, still a member of the Surgeon General's Committee, told Davis that there was absolutely no way that he could have contracted polio from taking the vaccine. The medical journals and government documents which Davis reviewed uniformly represented that it was impossible to prove that the vaccine caused an individual polio case.

When Davis was discharged from the Veterans Hospital on October 25, 1963, his case was diagnosed as polio, due to undetermined cause. (Appendix F, p. A-29.) In a June 26, 1964 letter to the Communicable Disease Center, the Director of Idaho's Preventive Medicine Division stated with respect to the cause of Davis's paralysis:

> The etiology of this case of paralysis has not been determined and a large number of virus diseases are to be considered. The present diagnosis of

> lower neuron disease with paralysis--etiology unknown --is the continuing diagnosis by this office of this interesting case.

(Emphasis added.) (Appendix N, pp. A-126-127.) Davis's case was never officially reported as polio by the Idaho Department of Health. (Appendix F, p. A-38.) Only thirteen months before Dr. Kirschstein's first deposition, the Surgeon General's Committee released the last of a series of reports in which it consistently represented that it was not possible to prove an individual case was caused by the vaccine. (Appendix A, p. A-17.)

The foregoing evidence clearly was sufficient to create an issue of fact whether Davis knew, prior to Dr. Kirschstein's deposition in October, 1965, the cause of his paralysis. If he did not know the cause at that time, then there can be no doubt that his cause of action did not accrue under § 2401(b) until 1973 when he learned of the existence and

results of the second test on Lot 35. Judge Tang correctly read the record to suggest that "Davis was still struggling to determine the cause of his injury by the critical date in October, 1963, and well beyond." (Emphasis added.) (Appendix A, p. A-17.)

If the cause of action did not accrue prior to the Kirschstein deposition, then it could not have accrued prior to 1973, because Dr. Kirschstein in her first depositon failed to produce the crucial piece of evidence on which Davis's claim rests. Without evidence of a defect in the particular lot from which he was vaccinated Davis had no cause of action against the government, because the Committee's reports had indicated the possibility of vaccine-induced polio, although the government continuously represented that this fact could not be proven in a given case. Thus to recover against the

government Davis had to show that a defect in Lot 35 rather than a generic property of Type III vaccine was the cause of his injury. Of course, without the results of the second test on Lot 35 Davis lacked the critical evidence needed (1) to prove a defect in that lot and (2) to refute the government's assertions that it was not possible to prove that a particular polio case was vaccine-induced.

An important point in this Court's decision in Kubrick was the ready availability outside government channels of information pertaining to the cause of plaintiff's injury:

> That he has been injured in fact may be unknown or unknowable until the injury manifests itself; and the facts about causation may be in the control of the putative defendant, unavailable to the plaintiff or at least very difficult to obtain. The prospect is not so bleak for a plaintiff in possession of the critical facts that he has been hurt and who has inflicted the injury. He is no longer at the mercy of the latter. There are others who can tell him if he has been wronged, and he need only ask.

(Emphasis added.) 100 S.Ct. at 359. Kubrick and this case are at opposite ends of the spectrum of available alternative sources of information. For Kubrick it was a simple matter of consulting physicians in his community. For Davis it was totally different. The government continuously had exclusive control of the critical evidence on causation and never voluntarily disclosed that information to Davis. Moreover, unlike Kubrick, a Committee formed by the government told Davis there was no way to prove that his injury was caused by the drug involved. Davis simply had no alternative source of information about the cause of his injury.

The Surgeon General's Committee was made up of some scientists who worked for the government and others who did not. Unlike the medical procedure involved in Kubrick, which was common knowledge both within and without government circles, only the Surgeon General, the Committee

and the DBS had access to the critical data concerning the polio immunization program.

In Kubrick the Court questioned plaintiff's diligence, stating, "Kubrick need only have made inquiry among doctors with average training and experience. . . to have discovered that he probably had a good cause of action. The difficulty is that it does not appear that Kubrick ever made any inquiry. . . ." (Emphasis added.) 100 S.Ct. at 360. By contrast, the record in this case discloses that Davis exercised diligence of the highest order in attempting to determine the cause of his paralysis.

It is well established that a dispute over the facts regarding the date on which a statute of limitations commences to run precludes summary judgment for defendant. Marshall v. Kimberly-Clark Corp., 625 F.2d 1300 (5th Cir. 1980); Camire v. United States, 535 F.2d 749 (2d

Cir. 1976). On this record Davis is entitled at a minimum to trial on the question when he knew of both his injury and its cause within the meaning of Kubrick. We think the record shows that as a matter of law his cause of action did not accrue until 1973, that his action was timely filed in April of 1974, and that he is entitled to remand for a full trial on the merits. This Court should accept review of this case because of the government's immense superiority in knowledge and resources in this field and the fundamental implications of fairness which those considerations entail, both in this case and others likely to follow.

III.

THE DECISION BELOW CONFLICTS WITH SETTLED FEDERAL LAW WHICH TOLLS STATUTES OF LIMITATIONS WHERE THE GOVERNMENT CONCEALS FROM A PLAINTIFF EVIDENCE WHICH IS CRUCIAL TO HIS CAUSE OF ACTION.

Under the concealment doctrine a statute of limitations is tolled where the defendant conceals facts essential to

plaintiff's cause of action. Rahn v. United States, 222 F.Supp. 775 (S.D.Ga. 1963). The concealment doctrine is read into every federal statute of limitations. Public Service of New Mexico v. General Electric Co., 315 F.2d 306 (10th Cir.), cert. denied, 83 S.Ct. 1695 (1963). The doctrine has been applied specifically to the Federal Tort Claims Act. E.g., Rahn, supra.

In this case the government concealed from Davis both (1) the results of the second test on Lot 35 and (2) the fact that one could prove, through evidence of neurovirulence test results, that a polio case was caused by a defect in a particular vaccine lot. The results of the second test constituted the crucial evidence on the elements of both causation and the government's breach of duty. Without this evidence Davis could not prove that his injury was caused by this

particular lot and thereby establish liability of the government.

The facts of Rahn, supra, are analogous to the circumstances of this case. In Rahn plaintiff suffered disfigurement of her arm because of the negligence of government doctors. She sought the government's medical records regarding her case, but was not furnished them until more than two years had passed from the time of her injury. These records comprised the only evidence of negligence, and the court held that the statute of limitations did not commence to run until she obtained the critical documents.

Likewise, in this case the federal government had exclusive possession of the relevant information so that the government's concealment made it impossible for Davis to pursue an action against the United States. Accord, Spevack v. United States, 390 F.2d 977 (Ct.Cl. 1968) (statute of limitations tolled

where Atomic Energy Commission concealed from plaintiff fact that Commission used his invention). See also Toal v. United States, 438 F.2d 222 (2d Cir. 1971) (statute of limitations tolled where government doctor failed to note in medical records that he did not remove from plaintiff's body a chemical contrast medium used to perform surgery).

It is clear that the government concealed the results of the second test during the 1965 deposition of Dr. Kirschstein, but the majority below rejected this position, asserting that the two-year period had elapsed prior to the deposition. The majority's position ignored entirely the substantial evidence in the record, recited by Judge Tang in his dissent and summarized in this petition, which shows that on several occasions in 1964, less than two years before the first Kirschstein deposition, Davis was still attempting to determine the cause of his injury.

As late as September 30, 1964, only thirteen months prior to the deposition, the government once again stated that it was not possible to prove that an individual case was caused by the vaccine. It is clear that the cause of action had not accrued at the time Dr. Kirschstein's deposition was taken in October, 1965.

Addressing the concealment doctrine, the majority below also stated:

> It may well be that the government was negligent in maintaining and publishing records. However, failure of the government to ascertain and publish the fact of its negligence is hardly sufficient to constitute fraudulent concealment.

(Appendix A, p. A-12.) The majority would equate the Surgeon General's Committee with the ordinary civil lawsuit where defendant does not acknowledge his own negligence. This view completely ignores the compelling social significance of this case--the government's role as guardian in the administration of a nationwide program affecting millions of citizens.

Without question the government did have the duty to disclose to the public that it was possible to prove that a particular lot of vaccine, as distinguished from a uniform property of the generic Type III strain, could cause the disease. Further, the government had the obligation to provide to individual participants all information relating to injuries received by them.

The main purpose of the neurovirulence testing was to insure safety of the vaccine and thus to protect people from contracting the disease from the vaccine. The regulations prohibited the release of a lot whose neurovirulence exceeded that of the reference virus. Yet the Committee consistently represented that there was no possible way to prove a causal connection between ingestion of a particular lot and the onset of polio. The existence of and reasons for government standards for neurovirulence, as well as the

results of the second test on Lot 35, were acutely material to the question considered by the Committee whether a causal connection could be proved between a case of polio and ingestion of vaccine.

The silence of the government's reports, in combination with non-disclosure of the second test, concealed from Davis an essential element of his cause of action--that a defect could exist in a particular lot and that such a defect could be proved to have caused the contraction of polio. Thus at the time he filed his lawsuit against Wyeth in July, 1964 plaintiff could not have known that there was a provable defect in Lot 35 and a causal connection between his injury and that defect.

In view of the government's complete control over the polio immunization program, to permit the government to invoke the statute of limitations in this case would set a precedent inconsistent with

Kubrick and existing federal law on the concealment doctrine and violative of fundamental fairness and the public's right to rely on the government's good faith.

CONCLUSION

This Court should review this case in light of the important questions it presents concerning the government's duties to the public in the administration of nationwide programs affecting the public health. The majority's decision incorrectly applies Kubrick, and, if allowed to stand, could cause serious confusion among the federal courts in the construction of the statute of limitations in future cases. To let stand the Ninth Circuit's judgment would effectively sanction an abuse of the government's great power over the lives of individual citizens and would constitute a dangerous precedent inimical to the spirit of individual rights.

For all of the foregoing reasons, this Court should grant the Petition for Certiorari.

Dated: August 25, 1981.

RESPECTFULLY SUBMITTED,

By Robert M. Tyler, Jr.
Robert M. Tyler, Jr.
(Counsel of Record)

By Blaine F. Evans
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APPENDIX A

IN THE UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

Glynn Richard Davis
Plaintiff-Appellant,

v.

UNITED STATES of America
Defendant-Appellee.

OPINION
No. 77-1942

(Argued and Submitted Dec. 12, 1979)
(Decided April 20, 1981)

Appeal from the United States District Court for the District of Idaho
Before: MERRILL, TANG and SCHROEDER, Circuit Judges

Background

The Sabin Type III oral polio vaccine was administered to appellant Davis as part of a nationwide campaign initiated by the government of the United States to eradicate paralytic poliomyelitis (polio) in this country. Mass immunization centers were established in cooperation with with state and local medical authorities,

and the campaign was widely publicized.[1] The Division of Biologic Standards (DBS) of the National Institutes of Health, a part of the United States Department of Health, Education and Welfare, was charged with testing and licensing manufacture of the vaccine; pursuant to 42 C.F.R. § 73.110 et seq.

The vaccine was administered to appellant Davis at one of these centers in March, 1963. Within thirty days, appellant was paralyzed from the waist down and exhibited other symptoms of polio. Davis brought suit against the manufacturer of the drug, Wyeth Laboratories, Inc., in 1964.

In the course of that litigation, in October, 1965, defendant Wyeth Laborato-

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[1]This mass immunization program is described in Davis v. Wyeth Laboratories, Inc., 339 F.2d 121, 123-25 (9th Cir. 1968), a previous action brought by this plaintiff against the manufacturer of the vaccine he ingested. The district court initially gave judgment for the manufacturer; this court reversed and remanded. The parties settled out of court before the case went to trial a second time.

ries, Inc., noticed the deposition of Dr. Ruth Kirschstein, the chief of the pathology section of the laboratory of Viral Immunology, DBS, accompanied by a subpoena duces tecum ordering her to bring to the deposition, inter alia, all records of DBS relating to lot No. 03503 of the Sabin Type III oral polio vaccine. The vaccine ingested by Davis was from this lot. Appellant's attorney was present at this deposition. Dr. Kirschstein brought with her records documenting the results of a single neurovirulence test;[1] the results fell within acceptable limits.[2]

[1]Each lot of vaccine was subjected to various tests by DBS. The so-called neurovirulence test, at issue here, involved administering the vaccine to thirty monkeys. After a seventeen-to-twenty-day observation period, the monkeys were destroyed and the brain or spinal cord of each monkey, depending on which had been injected with the vaccine, was removed and the tissue examined under a microscope for lesions. Lesions were graded on a scale of severity from one to four; if the number of monkeys developing lesions and the severity of the lesions fell within DBS standards, the lot was deemed to have satisfied the neurovirulence test.

[2]The test results revealed by Dr. Kirschstein at the October, 1965, deposition indicated that one monkey had developed lesions classified "one" and

Appellant alleges that not until 1973 did he learn from an attorney representing a plaintiff in another suit[4] that DBS had conducted another neurovirulence test on lot No. 03503, and that the results of that test did not fall within the acceptable range.[5] In April, 1973, appellant filed a notice of claim under the Federal Tort Claims Act (FTCA) 28 U.S.C. § 1346 et seq., and in April, 1974, brought the instant action in the court below.

The district court granted summary judgment for the United States, holding that Davis' suit was barred by the two-year statute of limitations which applied to all actions brought under the FTCA. 28

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another monkey had developed lesions classified "three"; these results were within the acceptable range under the DBS standards.

[4]Griffin v. United States, 351 F.Supp. 10 (E.D.Pa. 1972), aff'd 500 F.2d 1059 (3d Cir. 1974).

[5]One monkey developed lesions classified "four"; appellant contends that this was not within the acceptable range under the DBS standards.

U.S.C. § 2401(b).

Davis appeals, contending that either: (1) the cause of action did not accrue until he learned, in 1973, of the facts indicating the government's responsibility for his paralysis; or (2) the statute was tolled by the government's fraudulent concealment of the results of the second test.

We affirm the district court's grant of summary judgment.

Accrual of the Action

A two-year statute of limitations applies to all suits brought under the FTCA. 28 U.S.C. § 2401(b).[4] Appellant contends, however, that under the so-called "discovery rule" applied in medical mal-

[4]The statute was amended in 1970 to provide that a tort claim against the United States shall be barred unless written notice is provided to the appropriate federal agency within two years or unless a suit is instituted within six months of the mailing of notice of final agency action. Previously, the statute had simply required that an action be begun within two years of the time when it accrued. As will be apparent, the result in the present case is the same under either form of the statute.

malpractice cases, the cause of action did not accrue and the statute did not begin to run until he learned, in 1973, of the results of the second neurovirulence test. United States v. Kubrick, 444 U.S. 111, 100 S.Ct. 352, 62 L.Ed.2d 259 (1979), is cited in support of the proposition that the action accrues when the plaintiff learns, or, in the exercise of reasonable diligence should have learned, of his injury and of the actions that caused it. 444 U.S. at 123-24, 100 S.Ct. at 360-61. While the present case is not technically one involving medical malpractice, it is in many ways similar to such an action,[3] and we will assume, arguendo, that it should be assimilated to the category of medical malpractice for statute of limitations purposes. Nonetheless, we conclude that appellant's claim is barred by the statute.

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[3] See Hammond v. United States, 388 F.Supp. 928, 932 (E.D.N.Y. 1975).

The general rule in tort law is that the claim accrues at the time of the plaintiff's injury. In the area of medical malpractice this has been felt to be unduly harsh in those cases where the fact of injury remains undisclosed. The rule accordingly has widely been modified to provide that a claim does not accrue until the injury has manifested itself. Urie v. Thompson, 337 U.S. 163, 69 S.Ct. 1018, 93 L.Ed.2d 1282 (1949). The Restatement (Second) of Torts § 899, Comment e, quoted in United States v. Kubrick, supra 444 U.S. at 120 n.7, 100 S.Ct. at 358 n.7, reflects this change:

> "In a wave of recent decisions [it has been held] that the statute must be construed as not intended to start to run until the plaintiff has in fact discovered the fact that he has suffered injury or by the exercise of reasonable diligence should have discovered it."

In Kubrick, the Court assumed that the discovery rule should be further modified to provide that accrual does not occur, and

thus that the statute of limitations does not commence to run, until the plaintiff has discovered, or, in the exercise of reasonable diligence should have discovered, both his injury and its cause.[8] The Court noted that "the United States was prepared to concede as much for present purposes," id. at 120-21, 100 S.Ct. at 358-59.) The question presented was whether the rule should be still further extended to defer accrual until the plaintiff had, or, in the exercise of reasonable diligence should have had, knowledge of the defendant's negligence. The Court approached this question as one involving the construction of § 2401(b). It stated:

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[8]This rule is followed in this and most other circuits. Hungerford v. United States, 307 F.2d 99, 102 (9th Cir. 1962). Accord, Exnicious v. United States, 563 F.2d 418 (10th Cir. 1977); Bridgford v. United States, 550 F.2d 978 (4th Cir. 1977); Jordan v. United States, 503 F.2d 620 (6th Cir. 1974); Toal v. United States, 438 F.2d 222 (2d Cir. 1971).

> "[We] are not free to construe it so as to defeat its obvious purpose, which is to encourage the prompt presentation of claims. [Citations omitted]. We should regard the plea of limitations as a 'meritorious defense, in itself serving a public interest.' [Citations omitted]."

The Court then made it plain that it was not prepared to go further than the government concession. It refused to defer accrual until fault as well as injury and cause had been discovered; it would not hold that "the statute is not to run until the plaintiff is led to suspect negligence." Id. at 124, 100 S.Ct. at 124.

[1] With knowledge of the fact of injury and its cause the malpractice plaintiff is on the same footing as any negligence plaintiff. The burden is then on plaintiff to ascertain the existence and source of fault within the statutory period. It follows that diligence or lack of diligence in these efforts is

irrelevant. In the absence of fraudulent concealment it is plaintiff's burden, within the statutory period, to determine whether and whom to sue. Kubrick makes this plain. Once a plaintiff knows that harm has been done to him, he must, the Court states, "determine within the period of limitations whether to sue or not, which is precisely the judgment that other tort claimants must make. If he fails to bring suit because he is incompetently or mistakenly told that he does not have a case, we discern no sound reason for visiting the consequences of such error on the defendant by delaying the accrual the claim until the plaintiff is otherwise informed or himself determines to bring suit, even though more than two years have passed from the plaintiff's discovery of the relevant facts about injury." Id.

[2] In the present case, appellant was aware in April, 1963, that he had been injured and that the Sabin vaccine was the likely cause of his injury.[9] With knowledge of the fact of injury and its cause, appellant was at the time of his injury placed on the same footing as other negligence plaintiffs. The claim, then, accrued at the time of injury and the statute started to run. It was up to him to "determine within the period of limitations whether to sue or not." Id.

We conclude that in the absence of fraudulent concealment, appellant's claim against the United States was barred by limitations.

Fraudulent Concealment

[3] Appellant contends that even if the cause of action accrued prior to 1973, the statute was tolled by the

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[9]At the very latest, he was certainly aware that the vaccine was the cause in 1964, when he brought suit against Wyeth Laboratories alleging that such was the case.

government's fraudulent concealment of the results of the second test during the October, 1975, deposition of Dr. Kirschstein. This argument fails, since the two-year period had already elapsed.

Appellant also argues that certain press releases and reports by the government indicating that there was no probable link between the taking of the vaccine and subsequent polio cases amounted to fraudulent concealment. This contention is meritless.[18] It may well be that the government was negligent in maintaining and publishing records. However, failure of the government to ascertain and publish the fact of its negligence is hardly sufficient to constitute fraudulent concealment. See Rutledge v. Boston

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[18]These press releases and reports might have served also as additional notice to appellant of the government's involvement in his claim.

Woven Hose & Rubber Co., 576 F.2d 248, 250 (9th Cir. 1978).

We conclude that appellant's action was barred by the applicable statute of limitations. The decision of the district court granting summary judgment is affirmed.

TANG, Circuit Judge, dissenting.

I respectfully dissent. Quite simply, the record fails to support the majority's assertion that "appellant was aware in April 1963, that the Sabin vaccine was the likely cause of Davis' injury." First, although Davis contacted polio in April 1963, he was hospitalized until October 25, 1963, and it is unclear when he had sufficiently recovered to be aware of anything. At best, the record indicates that Davis was functioning again in "approximately June, 1963" when he began to write letters inquiring about his

disease. Clerk's Transcript Vol. IA, at 243.

More importantly, although Davis may have wondered in the summer of 1962 if the vaccine had induced his disease, "questioning" and a "knowing" causation cannot be equated. The Kubrick court plainly held that the statute begins to run only when a plaintiff is "armed with the facts about the harm done to him . . ." 444 U.S. at 123, 100 S.Ct. at 360. In other words, the plaintiff must be in "possession of the critical facts that he has been hurt and who has inflicted the injury" because "the facts about causation may be in the control of the putative defendant, unavailable to the plaintiff or at least very difficult to obtain." Id. at 122, 100 S.Ct. at 359 (emphasis added). In Kubrick, the plaintiff had surgery in April and developed a hearing loss in mid-June. In succeeding months, he consulted several specialists who

diagnosed his malady as "bilateral nerve disease." Finally, in January (some 7 months after injury), a doctor told Kubrick that it was "highly possible" that a treatment administered after surgery caused his deafness. At that point, the court held, Kubrick knew of his injury and its cause and the statute began to run.

Here, Davis may have suspected that the vaccine caused his disease (just as Kubrick may have suspected his recent surgery was in some way connected), but apparently no one, much less a doctor, would even suggest a "high possibility" that the two events were causally linked. To the contrary, all authorities consulted apparently assured Davis that oral Sabin vaccine could not be proved to cause the disease. For example, sometime in October, 1963, still searching for the cause of his disease, Davis wrote to the Washington

State Department of Health. In recounting his story, he stated:

> During the last six months I have had around 20 Drs. check me and everyone of them have said I was paralyzed, which I was just a little bit aware of. Not one of them would say a damn thing or admit it could have been due to the cube that was the cause of my illness . . . [sic]

Clerk's Transcript, Vol. IA, at 286.

Consistent with this description, on October 25, 1963, Davis was discharged with a diagnosis of paralytic poliomyelitis "due to undetermined cause". Id. at 241. Interestingly, in fact, the Idaho State epidemiologist refused to report Davis' case as poliomyelitis, and, in the Fall 1964, was still diagnosing Davis' disease as "lower neuron disease with paralysis--etiology unknown". Id. at 245.

Moreover, the scientists to whom Davis wrote, and the articles he read, failed to suggest a causal connection

between the vaccine and the paralysis. For example, an HEW doctor stated in an article published in June 1963 that "no evidence has been adduced to show that this vaccine, composed of these strains, had ever caused the disease it was designed to prevent." Id. at 244. Similarly, in the summer of 1964, Dr. Sabin informed Davis "that there was absolutely no way" that he could have contracted polio from taking the vaccine. Id. at 246. See also id. (U.S. government committee report of September 30, 1964, stating that "it is not possible to prove that any individual case was caused by the vaccine and that no laboratory tests available can provide a definitive answer.)

The record available to me, then, suggests that Davis was still struggling to determine the cause of his injury by the critical date in October 1963, and well beyond. In any event, at the least

the question when Davis knew (1) of his injury (paralysis) and (2) its cause (the vaccine) should be a factual determination for the jury, and I would reverse the premature grant of summary judgment. Such a result is justified since the Government, as the moving party, has failed to carry its burden of demonstrating the absence of a genuine issue of material fact. See also Marshall v. Kimberly-Clark Corp., 625 F.2d 1300, 1302 (5th Cir. 1980) ("A dispute over the facts surrounding the date the statute of limitations began 'would alone warrant denial of the motion for summary judgment.'"); see generally Yazzi v. Olney, Levy, Kaplan & Tenner, 593 F.2d 100, 103 (9th Cir. 1979).

In sum, I agree that the majority properly states the Kubrick rule. On this record, however, I fail to see how it can affirm the summary judgment.

APPENDIX B

IN THE UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

GLYNN RICHARD DAVIS,	)	
	)	No. 77-1942
Plaintiff-Appellant,	)	
	)	D.C. No.
vs.	)	Civil
	)	1-74-68
UNITED STATES OF AMERICA,	)	
	)	ORDER
Defendant-Appellee.	)	

Before: MERRILL, TANG and SCHROEDER, Circuit Judges

With regard to the petition for rehearing in the above matter, the panel has voted as follows: Judges Merrill and Schroeder to deny the petition for rehearing, while Judge Tang would grant panel rehearing; and Judges Tang and Schroeder have voted to reject the suggestion for rehearing in banc and Judge Merrill has recommended such rejection.

The full court has been advised of the suggestion for an in banc hearing, and no judge of the court has requested a vote

on the suggestion for rehearing in banc. Fed.R.App.P. 35(b).

The petition for rehearing is denied and the suggestion for a rehearing in banc is rejected.

APPENDIX C

U.S. DISTRICT COURT
DISTRICT OF IDAHO
Filed at ..... o'clock
JUN 22 1981
JERRY L. CLAPP, Clerk
Deputy

AFFIRMANCE

United States Court of Appeals
FOR THE NINTH CIRCUIT

GLYNN RICHARD DAVIS,

Plaintiff-Appellant,

vs.

UNITED STATES OF AMERICA,

Defendant-Appellee.

No. 77-1942

DC CV 1-74-68 RM

APPEAL from the United States District Court for the IDAHO District of IDAHO

THIS CAUSE came on to be heard on the Transcript of the Record from the United States District Court for the IDAHO District of IDAHO

and was duly submitted.

ON CONSIDERATION WHEREOF, It is now here ordered and adjudged by this Court, that the judgment of the said District Court in this Cause be, and hereby is affirmed.

A TRUE COPY
ATTEST 18 JUN 1981
Clerk of Court
by Deputy Clerk

Filed and entered April 20, 1981

APPENDIX D

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

GLYNN RICHARD DAVIS,	)	Civil No.
	)	1-74-68
Plaintiff,	)	
	)	ORDER ON
v.	)	DEFENDANT'S
	)	MOTION FOR
UNITED STATES OF AMERICA,	)	SUMMARY
	)	JUDGMENT
	)	
Defendant.	)	
	)	

This matter was duly brought on for hearing on March 15, 1977, on the Motion of the United States to Dismiss or in the Alternative for Summary Judgment. The Court concludes that matters outside the pleadings, that is, requests for admissions, interrogatories, and responses thereto, together with certain depositions, affidavits and attachments thereto and the record on file in Davis v. Wyeth Laboratories, Civil No. 3973, in this Court having been submitted and considered as a part of the record for purposes

of disposition of the government's motion and including in part the Affidavits of the Plaintiff Glynn Richard Davis, dated February 16, 1977, March 9, 1977, and March 22, 1977, together with attachments to those affidavits, the affidavit of Doctor Ernest A. Ager, dated February 25, 1977, and the affidavit of Blaine F. Evans, and further including in part a memorandum dated September 19, 1962, to Doctor George A. Hottle, Chief, LVI, from Ruth L. Kirschstein, Chief, Pathology, and the Results of Neurovirulence Test of Poliovirus Vaccine in Rhesus Monkeys dated September 19, 1962, consisting of four (4) pages, the matter is properly treated as a Motion for Summary Judgment pursuant to Rules 12(b) and 56 of the Federal Rules of Civil Procedure, and the Court being fully advised in the premises,

The Court finds and concludes that there exists no genuine or substantial issue of material fact with respect to

the Motion of the United States, and that the United States is entitled to judgment as a matter of law, for the reason that the instant action is barred by the applicable period of limitations and the Court lacks jurisdiction of the subject matter of the action. 28 U.S.C. § 2401(b).

IT IS, THEREFORE, ORDERED and this does order that the Motion of the Defendant United States of America for Summary Judgment be, and the same hereby is granted, that the Complaint and action herein be, and the same hereby is, dismissed with prejudice, and that the Defendant recover its costs of action.

Dated this 28th day of March, 1977.

/s/ RAY McNICHOLS
United States District Judge

APPENDIX E

UNITED STATES DISTRICT COURT FOR

THE DISTRICT OF IDAHO

GLYNN RICHARD DAVIS,	)	
	)	Civil No.
Plaintiff,	)	1-74-68
	)	
vs.	)	JUDGMENT
	)	
UNITED STATES OF AMERICA,	)	
	)	
	)	
Defendant.	)	

This matter having come before the Court upon the Motion of the United States to Dismiss or in the Alternative for Summary Judgment, the Court having heard further oral argument on March 15, 1977, by counsel for the parties, the Court having on this day entered its Order on said motion, and the Court being fully advised in the premises;

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that the Defendant United States of America hereby does, have judgment against the Plaintiff Glynn Richard Davis

and the complaint and action of said Plaintiff shall be, and the same hereby are, dismissed with prejudice and that the Defendant shall recover its costs in this action.

Dated this 28th day of March, 1977.

/s/ RAY McNICHOLS
United States District Judge

APPENDIX F

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

GLYNN RICHARD DAVIS, Plaintiff,	)	Civil No. 1-74-78
v.	)	AFFIDAVIT OF GLYNN RICHARD DAVIS IN SUPPORT OF MOTION TO RECONSIDER ORDER GRANTING SUMMARY JUDGMENT
UNITED STATES OF AMERICA, Defendant.	)	

STATE OF IDAHO)
) ss.
COUNTY OF ADA)

GLYNN RICHARD DAVIS, being first duly sworn under oath, deposes and says:

That I was a plaintiff-appellant in the case of Glynn Richard Davis, and Florence Davis v. Wyeth Laboratories, Inc., and American Home Products Corporation, Civil No. 3973, United States District Court for the District of Idaho, Appeal No. 20995 in the United States Court of Appeals for the Ninth Circuit. That I am the plaintiff in this action and make this affidavit in support

of my Motion to Reconsider Order Granting Summary Judgment.

That on or about March 17, 1963, I ingested Sabin Type 3 oral polio virus vaccine taken from Lot 35 manufactured by Wyeth Laboratories.

That approximately two weeks following ingestion of the vaccine, I contracted oral poliomyelitis, and after being treated in the Ashton Memorial Hospital, I was transferred to Idaho Falls, Idaho, where I was treated in the Idaho Falls Hospital; thereafter I was transferred to the Idaho Elks Rehabilitation Center, in Boise, Idaho, on May 14, 1963, and discharged on June 13, 1963, for admittance to the Veterans Administration Hospital of the United States government in Boise, Idaho.

That I remained in the Veterans Hospital until my discharge on October 25, 1963, but thereafter I returned daily for physical therapy, which continued until

May 29, 1964. At the time of my discharge from the Veterans Administration on October 25, 1963, my case was diagnosed as follows:

> "Paralytic poliomyelitis, convalescent stage, due to undetermined cause, with paralysis of the lower extremeties, and paresis of the right triceps."

The history of the licensing of Sabin oral polio vaccine and the mass immunization clinics that were held throughout the United States for the purpose of innoculating as many people as possible are graphically and correctly described in Davis v. Wyeth Laboratories, 399 F.2d 121 (9th Cir. 1968). In February, 1962 the Communicable Disease Center, (CDC) of the United States Public Health Service, and the Department of Health, Education and Welfare of the United States announced that Type 3 monovalent vaccine had been licensed and that a complete oral polio virus vaccine was thus available. The government, through

the CDC and HEW, announced at that time a campaign to completely eliminate paralytic poliomyelitis in the United States. Idaho, pursuant to the national plan, subsequently held clinics in the eastern part of the state, one of which was held at West Yellowstone, Idaho which was attended by me. Although doctors were supposed to be in attendance at the clinics, there was no doctor at the clinic in West Yellowstone, Montana, and the administration of the vaccine was delegated to a pharmacist.

On September 20, 1962, Luther Terry, M.D., Surgeon General Public Health Service, U.S. Department of Health, Education and Welfare, issued a report of the Surgeon General's Oral Poliomyelitis Vaccine Advisory Committee, which had been meeting in Washington, D.C. and reviewing the data concerning the occurrence of cases of poliomyelitis after the administration of poliomyelitis vaccine

during the calendar year of 1962. His report contained the following statement:

> "THE VACCINE ADMINISTERED TO THIS GROUP OF CASES WAS FROM SEVERAL LOTS AND WAS NOT PRODUCED BY ANY SINGLE MANUFACTURER."

Lot 35, from which was taken the vaccine which I ingested, was not yet licensed by the United States government for use. However, prior to issuance of the September 20, 1962 report, Lot 35 had been subjected to two tests by the federal government. The second test made on the vaccine revealed that it did not meet applicable government standards required for licensing and release of the vaccine to the public. This information was available to the Government on September 3, 1962, just two weeks before Dr. Terry issued his press release. I did not discover that the vaccine that I took did not meet government standards until approximately the time I filed my claim with the government for damages on

April 30, 1973. I was also unaware of the Surgeon General's Report, and not until the summer of 1963 did I discover it and the report of the Surgeon General's Committee issued on December 21, 1962. In the latter report the Committee stated:

> "IT SHOULD BE EMPHASIZED THAT THE COMMITTEE DOES NOT CONSIDER THAT AN INDIVIDUAL CASE CAN BE PROVED TO BE CAUSED BY THE VACCINE AND NO LABORATORY TEST HAS THUS FAR PROVIDED A DEFINITIVE ANSWER."

The Committee recommended that community plans for immunization be encouraged, using all three types of vaccine, that is Types 1,2 and 3.

In January of 1963, Lot 35 manufactured by Wyeth was released by the Surgeon General for distribution despite the fact that it did not meet government tests. After contracting the disease of polio and after sufficiently recovering to be able to do so, I began an intensive search in approximately June, 1963, to

determine why I was given a vaccine that would give me the the disease instead of preventing it. My wife is a registered nurse. In the process of my search I discovered the Surgeon General's Report of September 20, 1962, and the Committee's Report of December, 1962. In addition, some time in the summer of 1963, I read an article published on June 22, 1963 in the Journal of the American Medial Association. The article was authored by Henry Gelfand, M.D., Chief Enterovirus Unit, Communicable Disease Center, (CDC), United States Public Health Service, Department of Health, Education and Welfare. It is to be noted that it was the Communicable Disease Center which was charged with the responsibility of ascertaining the cause of the disease and the relationship between disease and the cause. It was Dr. Langmuir of the Communicable Disease Center who first proved epidemiologically

that the vaccine could cause the disease. My case against Wyeth, Civil No. 3973 in this Court, was finally tried on the sole issue of epidemiological proof that the vaccine had caused the disease.

There was no evidence available to me or to the public that the vaccine was not manufactured in accordance with government standards or that the vaccine with respect to any particular lot was defective in the sense that it would give the recipient the disease. The proof of causation in that trial, and the only proof available, was through the use of epidemiology. In Dr. Gelfand's article, at page 953, he stated the following after reviewing the various cases of polio in the United States:

> "Until recently, there was almost universal agreement that living, attenuated, oral polio virus vaccine (OPV) composed of the Sabin strains is safe, both to a primary vaccinee and to his contacts. This reputation for safety was one of the bases of the use of OPV in millions of persons in the U.S. and many

other countries. Although the thoroughness of routine reporting of morbidity and of special surveillance for possible vaccine-induced cases of paralytic poliomyelitis differed greatly among the various programs, no evidence has been adduced to show that this vaccine, composed of these strains, had ever caused the disease it was designed to prevent."

In the same article, Dr. Gelfand also stated:

"IF A HARMFUL RESULT WERE A GENERAL PROPERTY OF A VACCINE, NO ASSOCIATION WITH MANUFACTURER OR LOT CAN BE DEMONSTRATED WITH EITHER THE INACTIVATED OR LIVE, ATTENTUATED TYPES. IF, HOWEVER, THE DEFECT WERE NOT A UNIFORM PROPERTY, BUT A VARIABLE IN THE MANUFACTURING PROCESS, SUCH AN ASSOCIATION MIGHT BE DEMONSTRABLE."

Among the "compatible" cases studied by this special committee in 1962, no association with manufacturer or lot was found. Vaccines of all three American producers, and many different lots, were represented among these cases. And then, in Table 2 of the article, Dr. Gelfand stated that with respect to Sabin oral vaccine no

causal connection was demonstrated between a particular lot of vaccine and incidence of the disease.

In attempting to find out why I got the disease from the vaccine, I commenced in the early part of the summer of 1963 to write to numerous people, one of whom was Dr. Ernest Ager, the state epidemiologist for the state of Washington in Olympia, Washington. In response to my letter, I received one from Dr. Ager on October 30, 1963, which was introduced as plaintiff's Exhibit No. 25 at trial. In Davis v. Wyeth, Civil No. 3973 Dr. Ager referred my case to the Communicable Disease Center in Atlanta, Georgia. Dr. John Mather, the Idaho State Epidemiologist, has refused to report my case as one of poliomyelitis.

In 1964, the Surgeon General's Committee again met, and issued a new report, the new committee had greatly expanded its membership, and Dr. Ager was

a member of that committee. This report came out on September 30, 1964. Immediately prior to issuance of the report, in a letter dated August 17, 1964, Dr. Pierce Gardner, Chief of the Poliomyelitis Surveillance Unit, Department of Health, Education and Welfare, wrote Dr. Mather and told him that the Committee had met, and that my case was placed in the compatible probable group. Gardner stated that he thought that Mather would appreciate advance notice of the Committee's judgment in that Mather might wish to consider the Committee's opinion in reaching a final decision whether to include this case as an official reported case of poliomyelitis. This letter is plaintiff's Exhibit No. 17 in Davis v. Wyeth. Plaintiff's Exhibit No. 16 in that case is Mather's response to Dr. Gardner, in which he rejected the thinking of the Surgeon General's Committee on poliomyelitis, a committee composed

of the outstanding epidemiologists, neurologists and doctors in the field of poliomyelitis in the world, and stated that:

> "The present diagnosis of lower neuron disease with paralysis--etiology unknown--is the continuing diagnosis by this office of this interesting case."

My case never has been officially reported by the Idaho Department of Health.

In connection with this matter, I wrote numerous people including the Director of the Food and Drug Administration and the United States Public Health Service in Boise, Idaho. Attached to this affidavit as an exhibit is a copy of the letter which I wrote to Mr. J. W. Montieth, Administrator of National Health and Welfare, Ottowa, Ontario, Canada, which is typical of the letters that I sent out. Included in the correspondence which I sent to many doctors and scientists, both in and out of government, was a letter to Dr. Sabin

himself sometime in the summer of 1964; Dr. Sabin responded that there was absolutely no way that I could have contracted polio from taking the vaccine.

I authorized my attorney, Mr. Blaine Evans to interview Dr. Jonas Salk to see what information could be obtained from him. On July 18, 1964, my attorney, in company with Mr. Dale Clemons, another attorney in Boise, Idaho, visited Dr. Salk. Dr. Salk was unable to furnish any information that there was an identification of any particular lot with the vaccine induced poliomyelitis cases being reported around the United States.

In its report of September 30, 1964, the revised poliomyelitis committee included my case, and I was judged a probable compatible case of having the disease induced by the vaccine. The Committee expressly stated in its report, however, that no specific case could be proved to have been caused by the vaccine. The Committee specifically stated:

> "THE COMMITTEE CONCLUDED THAT IT IS NOT POSSIBLE TO PROVE THAT ANY INDIVIDUAL CASE WAS CAUSED BY THE VACCINE AND THAT NO LABORATORY TESTS AVAILABLE CAN PROVIDE A DEFINITIVE ANSWER. . . . THERE WAS NO APPARENT ASSOCIATION OF CASES WITH SPECIFIC LOTS OF VACCINE OR VACCINE PRODUCED BY A PARTICULAR MANUFACTURER."

Thereafter, in the Journal of the American Medical Association, October 5, 1964, Dr. Alexander Langmuir, who had first proven epidemiologically that there was an association between the vaccine and the disease, stated in reference to the Committee's findings:

> "There was no apparent association of cases with specific lots of vaccine or vaccines produced by a particular manufacturer."

In other words, at no time did the government ever state that a lot of vaccine that had been released and used had not met government standards and in fact, the United States stated continuously to the contrary that no specific lot of vaccine was involved in causing the disease. The

scientific thinking at that time was that the vaccine relationship to disease was a general property of the vaccine and not one resulting from improper manufacturing of the vaccine. With numerous individuals having been interviewed by my attorneys, with my own letter writing, and with the articles that I had read following my getting the disease, it was obvious at that time that the vaccine that had been released had met government standards and that the government could not have been at fault in releasing for public use the particular lot of vaccine from which I was vaccinated.

As a matter of fact, it was not until the Surgeon General's Report in September of 1964 (and read by me almost immediately upon its publication) that there was any concrete evidence that my own case could have been associated with the vaccine. Here again, it was thought or believed by the leading scientists and

doctors, including the very inventor of the vaccine, that there was no evidence that it would have made any difference as to which lot of vaccine I had taken. This was the proof that was adduced against Wyeth. The Circuit Court of Appeals itself in considering my case on appeal pointed out that the lot of vaccine that had been used had met government standards and that the only proof of vaccine-induced disease was epidemiological. Moreover, when the drug house took the deposition of Drs. Kirschstein and Murray in October of 1965, Wyeth's attorneys as well as my attorneys were assured in the deposition that the test administered by the Division of Biologic Standards of Lot 35 met government standards, but in fact Dr. Kirschstein failed to disclose, although asked about it, any other testing and kept secret the fact that a second test was conducted on Lot 35 which revealed that Lot 35 failed to

comply with government standards and therefore never should have been released to the public. The second test, all of which is more fully explained in the affidavit of Stanley Kops, which is incorporated herein by reference, shows that the lot of vaccine that was released by the government and that gave me the disease was a lot of vaccine that was too virulent by government standards to be released. It had not been sufficiently tamed or in the language of the scientists, attenuated to be released. Virulence means a capability of giving the disease to a human host. For this reason, when I first learned of the results of this second test, I immediately filed a complaint against the government on the ground that the government was at fault in releasing this defective lot of vaccine and the government's release of Lot 35 in violation of its own regulations caused me to get the disease.

Following my trial in Davis v. Wyeth, certain exhibits were withdrawn from the file of the court at my request. I have examined these exhibits and they are the same documents offered into evidence at that time, and as a part of this affidavit, I now list these documents and include them in this affidavit:

EXHIBITS ADMITTED OR OFFERED INTO EVIDENCE IN DAVIS V. WYETH

Exhibit No.:	Description:
2	Idaho Falls medical records
3	Idaho Elks' Rehabilitation Center Records
4	Veterans Administration Hospital records
5	Idaho State Laboratory Report
6	Chart of incidence of polio
7	Press Release from the Office of the Surgeon General, August 22, 1962
8	Surgeon General's Press Release of September 15, 1962.

12	State of Idaho, Dept. of Health, Bureau of Vital Statistics- statistics on polio
13	Chart on Polio Incidence in Montana 1962-1965
14	Letter from William F. Cashmore, M.D. Secretary of the Board of Medical Examiners State of Montana, to Blaine F. Evans
16	Letter from John Mather, M.D., Director of Preventive Medicine Division to Pierce Gardner, M.D. dated June 26, 1964
17	Letter from Pierce Gardner, M.D. to John A. Mather, M.D. dated August 17, 1964
21	September, 1963 issue of Northwest Medicine
23	Form used in Sabin vacination program
24	Record of plaintiff's vaccination with Type 1 Sabin vaccine
25	Letter from Ernest A. Ager, M.D. to Glynn R. Davis, dated October 30, 1963
29	Check for $74.50 dated April 1, 1963 to Del Simpson from Robert M. Brower

30	Check for $79.50 dated May 7, 1963 to Del Simpson from Robert M. Brower
32	Record of Wyeth Laboratories of shipment of Type 3 vaccine to Idaho Falls Medical association
33	Statement of $150.20 from J.N. Franklin
34	Invoice to KO Polio c/o J. N. Franklin dated April 30, 1963 for $32.00
35	K.O. Polio Expense invoice for $68.91 signed by J.N. Franklin
36	Summary of Invoices
37	PIE Freight Bill dated 3/6/63 to Bannock County Health Unit
38	Memorandum to All State and Territorial Health Officers from Dr. A.L. Gray, re: Statement on Type 3 Oral Poliomyelitis Vaccine, dated September 14, 1962
70	Morbidity and Mortality, Weekly Report, by U.S. Department of Health, Education and Welfare, Public Health Service, Vol. 13, No. 54

74 Poliomyelitis Surveillance Report No. 225 dated June 16, 1961

OTHER EXHIBITS OFFERED WITH THIS AFFIDAVIT:

1. The Association of Cases of Poliomyelitis with the use of Type III Oral Poliomyelitis vaccines (September 20, 1962) by Luther L. Terry, M.D.

2. Supplement to PSU 273, December 21, 1962

3. Oral Vaccine: Associated Paralytic Poliomyelitis, 1962, Journal of American Medical Association, by Henry M. Gelfand, M.D. Atlanta

4. Oral Poliomyelitis Vaccines, Report of Special Advisory Committee on Oral Poliomyelitis Vaccines to the Surgeon General of the PUblic Health Service, Vol. 190, No. 1 submitted by Dr. Alexander D. Langmuir

5. Letter dated 9/4/64 from Glynn R. Davis to Jay W. Monteith

6. Poliomyelitis Surveillance, Report No. 285 September 30, 1964

Although the Surgeon General's Committee was emphatic in issuing statements that no particular lot of vaccine was involved as a lot that induced the disease in the human host and that the disease producing characteristic of the vaccine manufactured, I do know, and I have been informed by Dr. Ernest Ager, and assert the fact that he, as well as the other members of the 1964 Surgeon General's Committee, was told by Dr. Roderick Murray, a member of the Committee and Dr. Kirschstein's superior at the Division of Biologics Standards, that all of the lots that had been released by the United States government for use by the public had met government standards. In fact, of course, as Dr. Murray well knew, or should have known, Lot 35 did not.

/s/ GLYNN RICHARD DAVIS

SUBSCRIBED AND SWORN to before me this _____ day of February, 1977.

_____
Notary Public for Idaho
Residing at Boise, Idaho

APPENDIX G

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

GLYNN RICHARD DAVIS,	)	
	)	
Plaintiff,	)	Civil No. 1-74-68
	)	
v.	)	
	)	AFFIDAVIT OF
UNITED STATES OF AMERICA,	)	STANLEY P. KOPS
	)	
Defendant.	)	
	)	

COMMONWEALTH OF PENNSYLVANIA:

COUNTY OF PHILADELPHIA:

Stanley Paul Kops, Esquire, being duly sworn according to law deposes and says that he is a member of the law firm of Freedman, Browosky and Lorry, who were counsel for the plaintiffs in the case of Griffin v. United States of America, 351 F.Supp. 10, -F.2d- CA3, 1974, and that in the trial of Griffin v. United States of America, documents were introduced into evidence which showed that Lot 35 of Wyeth Type III did not comply with the Code of Federal Regulations relating to Sabin Polio Vaccine; that the five licensing lots of Wyeth were lots 18, 19, 20, 23 and 24, that as of September 1, 1963, Wyeth Lots 23 and 24 would not have been released and in fact their release was in violation of the Code of Federal Regulations; that Lot 35 according to documents introduced in the Griffin trial was tested on two

occasions by the U.S. Government, once beginning June 1, 1962 and then again beginning August 17, 1962; that at the depositions of Dr. Roderick Murray and Dr. Ruth Kirschstein, in the case of Davis v. Wyeth, the U.S. Government employees only testified in regard to one test and only one test was marked as an exhibit. The test of August 17, 1962 which had a grade 4 monkey which had never been seen in regard to NA2 by the use of the intrathalamic test in the hands of the U.S. Government was never disclosed to plaintiff or plaintiff's counsel. According to the regulations this lot did exceed the NA2 standard. In addition in a meeting held on October 1, 1962 a comparison of the Wyeth Type III Vaccine with NA2 indicated that Wyeth Vaccine far exceed NA2 in regard to the number of grade 3 lesions and grade 4 lesions and the number of monkeys showing any grade whatsoever. Attached to this

affidavit is a letter from Paul Fehnel, Esq. indicating in paragraph nine that Wyeth Lots 23, 24, and 31 would not have been accepted for release as of August 12, 1963. Lots 23, 24 and 31 were among the four preceding lots to lot 35. Attached to this affidavit is a copy of the meeting of January 30, 1963 in where there is a discussion of Wyeth Type III Polio Vaccine testing in regard to Lots 35, 36 and 40. Lots 36 and 40 were the lots which followed Lot 35.

Attached to this affidavit is a copy of the minutes of the meeting of October 1, 1962 which indicates on page two of the said document that Wyeth Type III Vaccine far exceeded NA2. At no time did the U.S. Govenrment disclose to plaintiff or to plaintiff's counsel in the case of Davis vs. Wyeth the fact of the second test in regard to Lot 35; the fact that the four preceding lots did not qualify under the Code of Federal Regulations;

the fact that the five licensing lots did not comply with the Code of Federal Regulations. The attached documents are among the records furnished plaintiff's counsel by the U.S. Government in the matter of Griffin vs. U.S. of America.

Stanley Paul Kops, Esquire further deposes and states that the facts set forth above are true and correct to the best of his knowledge, information and belief and based on the review of the records of Griffin vs. U.S. of America and the depositions of Dr. Murray and Dr. Kirschstein in the case of Davis vs. Wyeth.

/s/ STANLEY PAUL KOPS

APPENDIX H

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

GLYNN RICHARD DAVIS, Plaintiff, vs. UNITED STATES OF AMERICA, Defendant.	) Civil No. 1-74-68) AFFIDAVIT OF ERNEST AGER IN SUPPORT OF MOTION TO RECONSIDER ORDER GRANTING SUMMARY JUDGMENT TO THE UNITED STATES

STATE OF WASHINGTON)
) ss.
County of King)

ERNEST AGER, being first duly sworn, deposes and says:

That some time in the summer of 1964, he was appointed by the Surgeon General of the United States to the Surgeon General's Special Advisory Committee on Oral Poliomyelitis Vaccine and that this Committee met some time in July, 1964.

That one of the members of this Committee was Dr. Roderick Murray, who at the time of the Committee's meeting in July,

1964, was Director of the Division of Biologics Standards of the National Institutes of Health.

That the subject of the Committee's study was the possible relationship between ingestion of Sabin vacine to incidence of the disease of polio.

That during the Committee's meeting in July, 1964, Dr. Murray represented to the Committee that all Type 3 Lots of the oral vaccine which had been tested by the Division of Biologics Standards up to the time of the July 1964 meeting had satisfied the government's neurovirulence standards.

/s/ ERNEST AGER

SUBSCRIBED AND SWORN to before me this 25th day of February, 1977.

/s/JOY E. McCORMICK
Notary Public for Washington
Residing at Lynnwood

CERTIFICATE OF DELIVERY

I hereby certify that on the 14th day of March, 1977, I hereby served a copy of the above and foregoing Affidavit of Ernest Ager in Support of Motion to Reconsider Order Granting Summary Judgment to the United States by delivering a true and correct copy of same to United States Attorney for the District of Idaho, Paul L. Westberg, 550 W. Fort Street, Boise, Idaho.

/s/ ROBERT M. TYLER, JR.

Result of Neurovirulence Test of Poliovirus Vaccine in Rhesus Monkeys

Wyeth Lot No. PO 35-III by Intrathalamic Inoculation Titer-log $10^{7.7}$ PFU /ml

Page 1

Test performed at DBS by DBS Test scored at DBS by DPS

Volume of Inoculum/monkey 1 ml (0.5 ml ETA)

Number of PFU inoculated/monkey 50,000,000 (1) (2)

(3) (4)

Date of inoculation 8/17/62

Date of sacrifice 9/3/62

Lot. & Inoc.	Monkey No.	Paralysis	Histologic Lesions of Poliomyelitis: Lumber 1	2	3	4	5	6	Av	Cervical 1	2	3	4	5	6	Av	Medulla lower	upper	Midbrain	Score of Polio Severity[a]	Spread[b]
10(1)	L5046	NP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
"	L5047	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
"	L5048	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
"	L5049	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0*	0	0
"	L5050	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0*	0*	0	0
"	L5051	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0*	0	0
"	L5052	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
"	L5053	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
"	L5054	"	3	3	2	3	2	3	3	3	3	3	3	2	2	3	4	4	3	4	3
"	L5055	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Total no. with polio/total no. of monkeys = Total Ratio[c] See next page/

* - non-specific lesions

\- - no lesions

Score key for lesions of poliomyelitis

1 - minimal

2 - mild

3 - moderately severe

4 - severe

Av. - arithmetic average of lumber or cervical lesion score

a - average lesion score in areas of or close to inoculation

b - average lesion score in area most distant from inoculation site

c - Total ratio: total lesion score over number of monkeys

NP - no paralysis

DPS DBS 9/19/62cw

APPENDIX I

Result of Neurovirulence test of Poliovirus Vaccine in Rhesus Monkeys

Lyth Lot No. PO 35-III by Intrathalamic inoculation Titer-log $10^{7.7}$ PFU/ml

performed at DBS by DBS Test scored at DBS by pnt

e of inoculum/monkey 1 ml (0.5 ml ETA)

e of PFU inoculated/monkey 50,000,000 (1) (2) Date of inoculation 8/17/62

(3) (4) Date of sacrifice 9/6/62

Page 2

Monkey No.	Paralysis	Histologic Lesions of Poliomyelitis																Score of Polio	
		Lumbar							Cervical							Medulla		Midbrain	Severity[a]	Spread[b]
		1	2	3	4	5	6	Av	1	2	3	4	5	6	Av	lower	upper			
1	L3056	HP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	L3057	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	L3058	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	L3059	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	L3060	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	L3061	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	L3062	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	L3063	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	L3064	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	L3065	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Total no. with polio/total no. of monkeys = Total Ratio[c]

See next page

non-specific lesions
no lesions
key for lesions of poliomyelitis
1 - minimal
2 - mild
3 - [illegible]

Av. - arithmetic average of lumber or cervical lesion score
a - average lesion score in areas of or close to inoculation
b - average lesion score in area most distant from inoculation site
c - Total ratio: total lesion score over number of monkeys

Result of Neurovirulence test of Poliovirus Vaccine in Rhesus Monkeys

Wyeth Lot No. PO 33:III by Intrathalamic inoculation Titer-log 10 7.7 PFU/ml

Page 3

rformed at DBS by DBS Test scored at DBS by DBS

of inoculum/monkey

of PFU inoculated/monkey 50,000,000 (1) (2)

(3) (4)

Date of inoculation 8/17/62

Date of sacrifice 9/7/62

Monkey	Paralysis	Histologic Lesions of Poliomyelitis																Score of Polio	
		Lumbar							Cervical							Medulla			
		1	2	3	4	5	6	Av	1	2	3	4	5	6	Av	lower	upper	Midbrain	Severity[a]	Spread[b]
L5066	NP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L5067	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L5068	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L5069	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L5070	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L5071	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L5072	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
[illegible]073	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L5074	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
L5075	"	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

c/30

Total no. with polio/total no. of monkeys = 2/30 Total Ratio[c] 5/30 | 1/30

on-specific lesions
o lesions
key for lesions of poliomyelitis
- minimal
- mild
- moderately severe
- severe

Av. - arithmetic average of lumber or cervical lesion score
a - average lesion score in areas of or close to inoculation
b - average lesion score in area most distant from inoculation site
c - Total ratio: total lesion score over number of monkeys
NP - no paralysis

APPENDIX J

THE ASSOCIATION OF CASES OF POLIOMYELITIS With the Use of Type III Oral Poliomyelitis Vaccines

A TECHNICAL REPORT

by

Luther L. Terry, M.D.
Surgeon General, Public Health Service

U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
September 20, 1962

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[1] The data in this report have been compiled by the Poliomyelitis Surveillance Unit, Communicable Disease Center, Public Health Service, U.S. Department of Health, Education, and Welfare. The information is based on routine morbidity and special poliomyelitis surveillance reports, individual case investigations and a wide variety of laboratory and field studies, all of which represent the work of several hundred practicing physicians, local, state and federal health officials, epidemiologists, and laboratory scientists. Their contribution is gratefully acknowledged.

On September 15, 1962, the Surgeon General's Oral Poliomyelitis Vaccine Advisory Committee met in Washington, D.C., and reviewed the data concerning the occurrence of cases of poliomyelitis after the administration of oral poliomyelitis vaccines during the current calendar year. After a full discussion of the problem the Committee unanimously recommended that the use of Type III vaccine be limited to preschool and school age children and to adults at high risk, i.e. those traveling to hyperendemic areas and those living in areas where Type III epidemics were present or impending. They advised that mass programs using Types I and II oral vaccines be continued for all age Groups.*

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*The members of the Special Oral Poliomyelitis Vaccine Advisory Committee who approved the recommendations are: Drs. David Bodian, John P. Fox, Archie L. Gray, William McD. Hammon, Hugh H. Hussey, Alexander D. Langmuir, Roderick Murray, John R. Paul, Edward B. Shaw, Joseph E. Smadel. Dr. Albert B. Sabin, also a member of the Committee, participated in its first two meetings on

The present report summarizes the information which was reviewed by the committee and upon which its recommendations were based. Included are: (1) a brief review of the use of poliomyelitis vaccines in the United States, particularly the use of recently licensed oral poliomyelitis vaccines; (2) an appraisal of the present poliomyelitis problem; and (3) a listing, in detail, of the cases of poliomyelitis that have occurred in association with the use of oral poliomyelitis vaccines. This information is being made broadly available to the medical and health professions at this time in order that they may have the opportunity for a full understanding of the basis for the recommendations.

Use of Poliomyelitis Vaccines:

The Type I oral vaccine was licensed for distribution in interstate commerce

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August 9 and 16, 1962. He was out of the country on September 15 and was thus unable to be present at the meeting on that date. The Surgeon General served as Chairman of the Committee.

on August 17, 1961; Type II vaccine on October 10, 1961; and Type III on March 27, 1962. Prior to these dates, experimental lots of the respective vaccines were employed in a number of small scale and some large scale community programs.

Since vaccine licensure, a great many community-wide vaccination programs have been carried out. The programs have ranged in size from those involving single small towns, to those which include metropolitan areas in several continguous counties, to an essentially statewide program in Massachusetts. The oral vaccines have also been employed for smaller programs among selected population groups and for routine use in private practice and health department immunization clinics.

In epidemic control, Type I vaccine was used immediately following release in the Syracuse, New York, area and, in 1962, in many counties of Texas; in

Mobile, Alabama; Pasadena, California; and several rural counties in Kentucky and Pennsylvania to abort existent or impending epidemics. Experimental lots of Type III vaccine were used in 1961 in outbreaks in Atlanta, Georgia, and in Newberry County, South Carolina. Commercial Type III vaccine was used in Washington County, Virginia, in 1962.

The estimated use of oral vaccines in the United States is summarized in table 1. Utilization of both experimental lots and the licensed product is shown. Since it was recommended that Type 1 vaccine be fed first and because many programs did not start until late spring, the estimates show a much greater use of this type of vaccine than Types II and III. Estimated use in community programs of the three types of vaccine by mouth is shown in figure 1.

In most areas the vaccine was offered to persons of all ages and found

wide acceptance among adults as well as children. In a few areas, as in Massachusetts, use of the oral vaccines in public programs was largely limited to children.

During the past 12 months, the inactivated (Salk) poliomyelitis vaccines (IPV) have continued to be used although less widely. Since April 1955, a total of 537 million doses of IPV has been distributed. A random sample survey of the population in September 1961 indicated that slightly more than 50 million persons in the population had received 4 or more doses of the inactivated vaccine.

Incidence of Poliomyelitis:

The annual incidence of reported cases of poliomyelitis by paralytic status from 1955 through 1961 is shown in table 2. The marked decline in paralytic cases can be attributed largely to the widespread use of the inactivated polio vaccine. During the first 9 months of

1962, the incidence of poliomyelitis has further declined as shown in table 3.

Present data indicate that for 1962, the paralytic poliomyelitis rate for those under 20 will be approximately 7.6 per million; for those over 20, about 0.9 per million. These rates will represent a record low for the 52-year period since the reporting began.

The further decline in the incidence of poliomyelitis in 1962 may be attributed to the steadily improved immunization status of the population resulting both from the continued use of inactivated polio vaccine and the wide use of oral vaccines.

The Occurrence of Cases Following Oral Vaccine:

With the licensing of Type I oral vaccine in August 1961, the poliomyelitis surveillance program of the Communicable Disease Center placed particular stress on the evaluation of reported cases of

poliomyelitis developing after vaccine use. It was recognized that when millions of persons participate in an immunization program, any of a variety of subsequent events might occur coincidentally but be attributed erroneously to the vaccine. This could be particularly true of an intercurrent disease such as aseptic meningitis that might simulate poliomyelitis and even poliomyelitis due to infection with wild polioviruses that had been acquired prior to the vaccination. The problem is compounded during the summer and early fall when many enteroviruses are actively circulating.

In epidemic control a number of cases of disease among vaccinees can be expected in the days immediately following an immunization program before there has been opportunity for immunity to develop. In nonepidemic areas, the frequency of coincidental cases should be lower, although not necessarily zero. If

vaccine is related in a causal way to the cases, the intervals between immunization and onset of disease should group with the expected 7- to 30-day incubation period of the disease.

Since August 17, 1961, when Type I oral vaccine became commercially available, there have been 62 cases of poliomyelitis officially reported to the Public Health Service in which oral polio vaccine had been administered within 30 days prior to the onset of symptoms.

During the epidemic in New York State in 1961, a total of 32 "under 30-day vaccinated cases" was reported. Most of these developed soon after administration of the vaccine, in fact, 15 within 6 days. The early appearance of these cases indicates a coincidental rather than a causal relationship to vaccination. Similarly, in South Carolina, Georgia, and Texas, a total of 17 "under 30-day vaccinated cases" was

reported. Again, most appeared soon after vaccination, 11 within 6 days, and do not suggest a causal relationship.

In the nonepidemic areas, a total of 16 "under 30-day vaccinated cases" has been reported. These have come from seven States. Two followed Type I vaccine, 1 followed Type II vaccine, and 13 followed Type III vaccine. Eleven of the 16 occurred between the 15th and 29th days. This finding warranted further consideration of the possibility of a causal relationship to the vaccine, particularly to the Type III vaccine.

The Advisory Committee directed special attention to these 16 under 30-day cases reported from nonepidemic areas. All available clinical, epidemiological, and laboratory information was reviewed. Each case was considered individually, and excluded or not excluded by group decision from further consideration as to the possibility of its

being vaccine induced. No case was excluded except by unanimous agreement of the committee members. Included for consideration were those cases clinically compatible with poliomyelitis which demonstrated any significant paralysis and in which laboratory findings to date were not inconsistent with a vaccine relationship. Descriptive data regarding these cases are summarized in table IV.

Of the two cases of poliomyelitis reported following Type I vaccine administration, only one (case 2) was thought by the Committee to be entirely compatible clinically with poliomyelitis. Of recent onset, the virologic studies on this patient are still in process. The clinical history of the other case (case 1) indicated it to be exceedingly mild and atypical. The patient experienced no known febrile illness, he was not hospitalized, and no cerebrospinal fluid

studies were performed. He recovered with no residual paralysis.

The single case reported following immunization with Type II vaccine was found to have a Type III virus in his stool. Since Type III vaccine had not been fed, it can be concluded that the infection was due to a wild virus.

Eleven of the 13 cases following Type III oral polio vaccine were considered by the Committee as possibly vaccine related. Of the two cases excluded, one (case 14) had an illness atypical for poliomyelitis with no functional impairment after 30 days. Both Type I and Type III polioviruses were recovered from the stool, 55 and 27 days respectively after Types I and III vaccines had been fed to the child. The Type I virus which was recovered was characterized as "wild-like" according to the results obtained by the modified Wecker and McBride tests. These tests are used to demonstrate

slight antigenic differences between poliovirus strains of the same type. Since the virus strains may, after a period of intestinal multiplication, show such a shift in the antigenic characteristics of the viruses, no definitive interpretation of this finding was possible. The second case (case 16) which was excluded from further consideration had an insignificant paralytic residual and no detectable Type III antibody in either acute or convalescent serum specimens.

From 6 of the 11 cases, Type III poliovirus was recovered from stool specimens. Five of the six were characterized as "vaccine-like" by the modified Wecker and McBride Tests. Although this finding was of interest, it unfortunately provided little help in determining whether the vaccine played a causal role. Each of these considered had been fed oral vaccine and, hence, might be expected to be excreting the Type III vaccine

virus which might appear by the modified Wecker and McBride tests to be, as noted above, either "wild-like" or "vaccine-like." Further, it is possible that the oral vaccine strain may have displaced a "wild" enterovirus which was, in fact, the etiological agent responsible for the paralytic illness. In summary, isolation of a Type III virus from the stool and demonstration of Type III antibodies in the patient's sera served to indicate only that the paralytic disease would not be incompatible with Type III vaccine-induced disease.

The 11 cases considered as possibly related to Type III vaccine feeding are between 16 and 52 years of age, with all but 3 of the cases over 30. The vaccine administered to this group of cases was from several lots and was not produced by any single manufacturer. Of the 11 cases, 3 occured in Oregon, 3 in Nebraska, 2 in Michigan, 2 in Ohio, and 1 in

New York State. The clinical illnesses in these patients range from significant to severe. No deaths occurred. Among the 11 cases, the entire spectrum of nonfatal paralytic illness characteristic of poliomyelitis was evident.

Discussion Summary:

Of the reported cases to date, 1 following Type I vaccine and 11 following Type III vaccine were considered by the Committee to be clinically consistent with paralytic poliomyelitis and with laboratory findings which could not exclude a possible relationship to the administration of oral vaccine.

As noted, a single case occurred within 30 days of Type I vaccine administration during a period of almost 9 months when approximately 20 million persons were fed Type I vaccine. This is wholly compatible with coincidental origin.

The 11 cases following Type III vaccine cannot all be assumed to be coincidental. The adult age distribution ranging from 16 to 52 years with eight of the cases over 30 years of age, and the clustering of the intervals from vaccine feeding to onset in the 2-3 week period suggest a vaccine relationship. For these reasons the Committee concluded that "there is sufficient epidemiological evidence to indicate that at least some of these cases have been caused by the Type III vaccines."

The incidence, assuming all cases to have been vaccine induced, is but 11 cases among more than 13 million fed. This is less than one case per million doses given. When the risk is related to age it is apparent that adults are exposed to a greater hazard than are children. Inadequate information on the age specific vaccine acceptance rate, however, makes it impossible to calculate a more

precise estimate of the risk at this time.

With the incidence of poliomyelitis at a low level in this country, the Committee therefore recommended that the Type III vaccine be restricted to pre-school and school age children and to those adults in high risk groups, such as those traveling to hyperendemic areas or in areas where a Type III epidemic is present or impending.

Since the vast majority of poliomyelitis cases occur among young children and since children are the principal disseminators of the virus, continued intensive immunization programs among this group are clearly indicated. If this group can be adequately immunized, the spread of the poliomyelitis viruses will be sharply restricted, if not essentially eradicated.

TABLE I.—*Estimated Use of Oral Poliomyelitis Vaccine (Sabin strains) in the United States*

	Type of vaccine (in 1,000's of doses)			
	I	II	III	Total
Experimental vaccines:				
Community prophylactic programs	*693	*612	*621	*1,926
Epidemic control	----	----	322	322
Licensed vaccines:				
Community prophylactic programs	12,392	3,622	9,492	25,506
Epidemic control	3,064	----	2	3,066
Other programs, routine immunization clinics and private practice	5,000	3,000	4,000	12,000
Totals	21,149	7,234	14,437	42,820

*Including trivalent vaccine.

TABLE II.—*Annual Incidence of Reported Cases of Poliomyelitis by Paralytic Status in the United States 1955–61*

Year	Number of reported cases			
	Paralytic	Nonparalytic	Unspecified	Total
1955	13,850	12,453	2,682	28,985
1956	7,911	6,555	674	15,140
1957	2,499	2,826	160	5,485
1958	3,697	1,941	149	5,787
1959	6,289	2,045	91	8,425
1960	2,525	626	39	3,190
1961	988	305	19	1,312

TABLE III.—*Incidence of Poliomyelitis by Paralytic Status in the United States January through 36th Week—1962 and Comparable Periods in Previous Years*

Paralytic status	1962	1961	1960	1959
Paralytic	393	454	1,200	3,122
Nonparalytic	78	151	368	1,394
Unspecified	29	77	167	440
Total	500	682	1,735	4,956

Figure 1

Estimate of the Number of Persons Fed
During Known Mass Community Oral Polio Vaccination Programs
by Month from Date of Licensure, United States

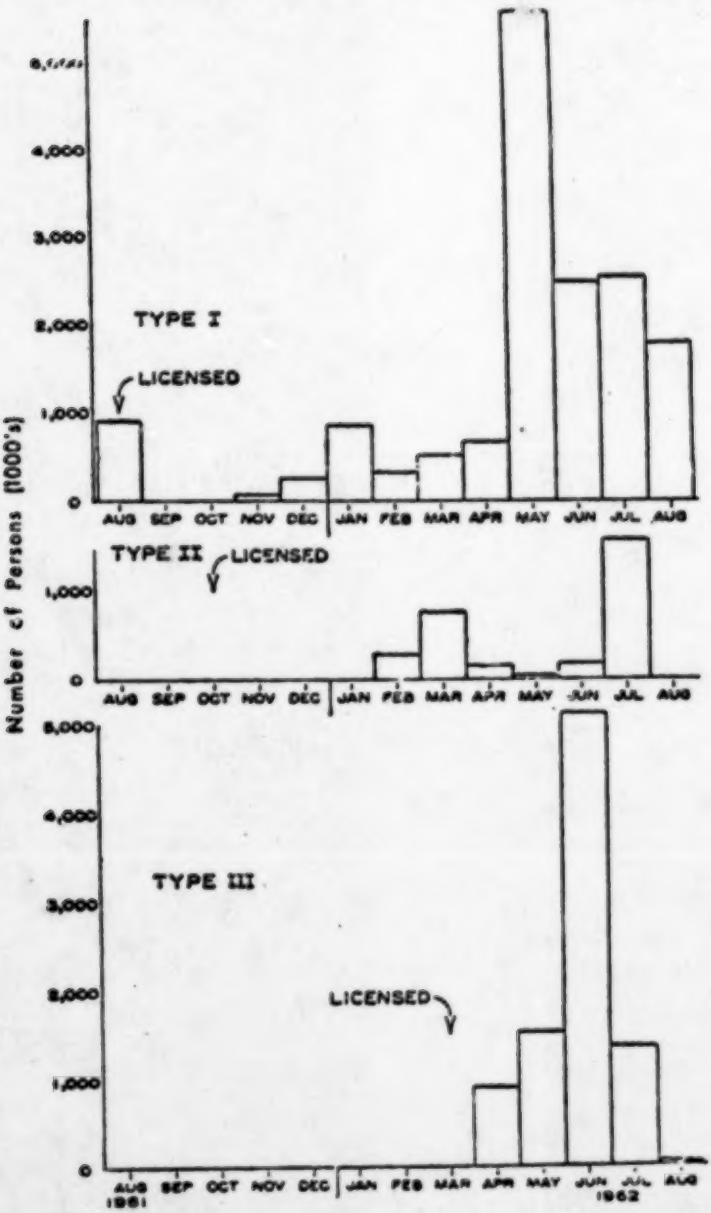

TABLE IV.—*Cases of Reported Paralytic Poliomyelitis Occurring Within 30 Days of the Administration of Oral Poliomyelitis Vaccines in Nonepidemic Areas January 1 to September 15, 1962*

Case No.	Age	Race	Sex	Doses IPV	Onset first symptom	Clinical severity	Interval from OPV (days)			Virus isolates		Antibody response	Committee[1] appraisal
							Type I	Type II	Type III	Type	Character		
Type I Vaccine													
1	3	W	M	2	5/29	1	23	.....	.....	I	Wild like	I	Excluded.
2	25	W	M	1	8/30	3	10	.....	.....	(**)	(**)	(**)	Compatible.
Type II Vaccine													
3	2	W	F	2	2/23	3	Over 90	8	.....	III	—	—	Excluded.
Type III Vaccine													
4	23	W	M	4	7/16	3	76	.....	17	III	Wild like	III	Compatible.
5	36	W	F	0	7/20	3	.....	.....	22	III	Vaccine like	III	Compatible.
6	18	W	F	5	7/1	3	34	.....	7	III	(**)	(**)	Compatible.
7	51	W	M	0	7/16	3	51	.....	22	0	—	(**)	Compatible.
8	37	W	M	0	7/23	3	43	.....	15	—	—	—	Compatible.
9	49	W	M	0	6/18	4	+90	.....	26	0	—	II & III	Compatible.
10	16	W	M	0	6/8	3	43	.....	15	—	—	—	Compatible.
11	36	W	M	0	7/15	4	.....	.....	21	0	—	I & III	Compatible.
12	48	W	F	0	5/5	4	34	.....	7	III	Vaccine like	III	Compatible.
13	39	W	M	0	5/21	4	50	.....	23	III	Vaccine like	—	Compatible.
14	6	W	M	0	5/25	1	54	.....	27	I	Wild like	—	Excluded.
										III	Vaccine like	—	
15	52	W	M	0	6/26	4	52	.....	19	III	Vaccine like	III	Compatible.
16	6	W	M	4	6/12	2	37	.....	5	I	(**)	I	Excluded.

**In process.

Key for severity:
1=Complete recovery, no residual paralysis.
2=Minor involvement.
3=Significant disability.
4=Severely disabled (bed, wheelchair, extensive bracing).

Key for virus and antibody studies:
0=Negative test.
—=Test not done.
Virus character was determined by the modified Wecker and McBride tests.

[1] Considered compatible with vaccine-induced disease where those cases clinically indistinguishable from poliomyelitis with some significant residual paralysis and laboratory studies not inconsistent with the possibility of vaccine relationship.

APPENDIX K

SUPPLEMENT TO PSU 273

December 21, 1962

A. Statement Released from the Office of the Surgeon General, December 19, 1962.

B. Report of the Special Advisory Commitee on Oral Poliomyelitis Vaccine to the Surgeon General. December 18, 1962

C. Line Listing of Cases Considered by the Committee.

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Surveillance Section
Epidemiology Branch
Communicable Disease Center
U.S.P.H.S.

A. Statement Released to the Press by the Office of the Surgeon General

Communities planning immunization campaigns against poliomyelitis are urged to move ahead, using all three types of Sabin oral vaccine with particular emphasis on children and young adults, Surgeon General Luther L. Terry of the Public Health Service announced today.

Dr. Terry said that this is the recommendation of the Surgeon General's Special Advisory Committee on Oral Poliomyelitis Vaccine which concluded its fifth meeting this year on December 18, and that he has accepted the Committee's recommendations.

The Committee stressed that special attention be given to children because they comprise the population group "in whom the danger of naturally occurring poliomyelitis is greatest and who serve

as the natural source of poliomyelitis infection in the community."

"The Committee feels and I wholeheartedly agree that of greatest importance is planning for the continuing vaccination of oncoming generations," the Surgeon General said. "This is the only way we will succeed in eradicating polio permanently."

The Surgeon General quoted the recommendation of the Committee with respect to vaccinations among adults:

"Because the need for immunization diminishes with advancing age and because potential risks of vaccine are believed by some to exist in adults, especially above the age of 30, vaccination should be used for adult only with the full recognition of its very small risk. Vaccination is especially recommended for those adults who are at higher risk of naturally occurring disease;

for example, parents of young children, pregnant women, persons in epidemic situations and those planning foreign travel."

Dr. Terry presided at the two-day meeting at which committee members reviewed all cases of suspected polio-like illness currently known to have been associated with the administration of oral polio virus vaccine of all three types in non-epidemic areas.

"In the oral and the Salk vaccines we have two established weapons against polio and we can, I believe, look forward to the day when polio is finally eliminated in this country," the Surgeon General stated. "With a total of around 650 cases reported this year, compared to almost 58,000 a decade ago, it is clear we are well on our way."

In commenting on the work of his Advisory Committee, Dr. Terry said: "The meticulous care with which members of this committee--all experts in the scientific disciplines

involved in the use of vaccines--have watched and evaluated developments in the widespread use of oral poliomyelitis vaccines is exemplary." They are rendering an invaluable service in advising us.

Members of the Surgeon General's Committee are: Dr. David Bodian, The Johns Hopkins School of Medicine; Dr. John Fox, Public Health Research Institute of the City of New York; Dr. Archie L. Gray, Secretary and Executive Officer, Mississippi State Board of Health; Dr. William MCD. Hammon, University of Pittsburgh; Dr. Hugh Hussey, Dean, School of Medicine, Georgetown University; Dr. Alexander Langmuir, Public Health Service, Communicable Disease Center, Atlanta, Georgia; Dr. Roderick Murray, Public Health Service, National Institutes of Health, Bethesda, MD; Dr. John Paul, Yale University School of Medicine; Dr. Albert Sabin, University

of Cincinnati; Dr. Edward D. Shaw, University of California School of Medicine; and Dr. Joseph E. Smadel, Public Health Service, National Institutes of Health, Bethesda, Md.

The report of the committee's findings and recommendations is attached.

B. Report of the Special Advisory Committee on Oral Poliomyelitis Vaccine to the Surgeon General, PHS. December 18, 1962

The Committee met to review all cases of suspect polio-like illness currently known to have been associated with the administration of oral poliovirus vaccine of all three types in non-epidemic areas. These included, in addition to cases previously considered, 25 cases newly discovered among persons fed vaccine and four cases among individuals in contact with vaccinated persons. Some of the cases previously accepted as "compatible" have been dropped from this category because of

additional clinical and laboratory evidence that has become available. New cases have been added to the "compatible" group where careful review has justified such action.

It should be emphasized that the committee does not consider that an individual case can be proved to be caused by the vaccine and no laboratory test has thus far provided a definitive answer. However, it has attempted to decide for each case whether or not it is "compatible" with the possibility of having been induced by the vaccine. Cases have been judged as "compatible" when three criteria were met: (1) onsent within a period (4-30 days after feeding) consistent with a reasonable incubation period; (2) an illness clinically consistent with paralytic polio; and (3) laboratory findings which do not exclude a vaccine relationship.

On the basis of data now available the total number of cases associated in time

with the direct administration of Type III vaccine and considered by a committee majority as "compatible" is now 11, of which 8 are over 30 years of age. Four cases were excluded as clearly unrelated to Type III vaccination; and seven cases were considered inconclusive as to a possible vaccine relationship.

The total number of cases associated with the administration of Type I vaccine and considered as "compatible" is seven, of which 4 are over 30 years of age. Ten cases were excluded; six were considered inconclusive. None of the three Type II associated cases was judged to be "compatible".

It should be noted that the total number of doses of oral vaccine given in non-epidemic areas during 1962 is approximately 31 million Type I, 19 million Type II and 15 million Type III. Hence, the maximum potential risk for Types I and

III is of the order of one per million or less overall, but higher for those over 30 years of age. For Type II there is still no indication of risk.

Consideration of the four cases in unvaccinated persons in household contact with vaccinees resulted in two being judged "compatible" and two "excluded". One additional "compatible" case occurred in a nonhousehold contact. Considering the large amount of vaccine administered and the known frequency of vaccine virus spread from vaccinated to unvaccinated persons, particularly within homes, it is concluded that contact spread has posed no significant hazard.

It is therefore recommended: (1) that community plans for immunization be encouraged, using all three types; and (2) that immunization be emphasized for children in whom the danger of naturally occurring poliomyelitis is greatest

and who serve as the natural source of poliomyelitis infection in the community. Because the need for immunization diminishes with advancing age and because potential risks of vaccine are believed by some to exist in adults, especially above the age of 30, vaccination should be used for adults only with the full recognition of its very small risk. Vaccination is especially recommended for those adults who are at higher risk of naturally occurring disease; for example, parents of young children, pregnant women, persons in epidemic situations and those planning foreign travel.

Of greatest importance is the continuing vaccination of oncoming generations.

C. Cases Considered by the Special Advisory Committee

As stated in the report of the Advisory Committee, all known cases of suspect polio-like illness associated in time with the

administration of the three types of oral polio vaccines outside of epidemic areas were reviewed. The line listings which appear below categorize the cases for consideration as occurring after the administration of Type I, Type II or Type III vaccine. Thus any case with onset more than 30 days after one type of vaccine administration but within 30 days of a second type received 2 reviews. Two cases, as indicated in the listing, were considered both as primary vaccinees and as contacts of vaccinees.

All cases considered have been listed in previous P.S.U. reports except for ten cases from California which have not yet been officially reported. These were considered from a special report prepared and submitted to the Committee by the California State Department of Public Health. The Committee appraisal on each individual case is indicated, based on the criteria listed in their report.

Cases of Polio-like Illness Following Oral Polio Vaccines Occurring Outside of Epidemic Areas in 1962 - Reviewed by the Surgeon General's Advisory Committee on Poliomyelitis Vaccines

\- No Specimen
0 No Isolate Obtained
** In Process

I. Cases Following Type I Vaccine

State	Age	Sex	Doses IPV	Days from Feeding of OPV to Onset of Illness[1] I	II	III	Virus Isolate Type	Virus Isolate Character	Antibody Response	Committee Appraisal
Calif.	8	M	4	2(7)			I	**	I	Excluded
Calif.(NR)[2]	11	M	4	?(4)			0		Inconclusive	Inconclusive
Calif.(NR)	32	M	0	(14)			I	**	I	Compatible
Calif.	42	M	0	8(11)			I	**	I	Compatible
Calif.	2	F	2	18(19)			I	**	I	Compatible
Calif.	58	M	0	25(26)			**		Inconclusive	Compatible[3]
Calif.(NR)	3	M	5	?(40)			I	**	**	Excluded
Calif.	7	F	6	22(25)			II[5]	**	Inconclusive	Inconclusive
Calif.(NR)	33	M	3	-2(12)			III	**	Inconclusive	Excluded
Calif.(NR)	30	M	3	14(23)			III	**	Inconclusive	Excluded
Calif.(NR)	4	F	?	-4(8)			I	**	Inconclusive	Excluded
Calif.(NR)	11	M	4	-8(6)			I	**	Inconclusive	Excluded
Calif.(NR)	33	M	0	9(13)			0		**	Inconclusive
Calif.(NR)	37	M	8	(97)	1	48	-		-	Excluded
Calif.(NR)	35	M	0	9(11)			I	**	**	Compatible
Ill.	16	M	?	4(6)			I	Non-Vacc.like (3 Specimens) Vaccine-like (1 Specimen)	I	Compatible
Iowa	14	F	3	(9)			I	Vaccine-like	I, II	Compatible
Mass.	7	M	5	(27)			I	Vaccine-like	Inconclusive	Excluded
Mass.	11	M	4	16(30)			-		-	Inconclusive

I. Cases Following Type I Vaccine (Continued)

- No Specimen
0 No Isolate Obtained
** In Process

State	Age	Sex	Doses IPV	Days from Feeding of OPV to Onset of Illness[1] I	II	III	Virus Isolate Type	Character	Antibody Response	Committee Appraisal
N.Y.(1)[4]	3	M	2	(23)			I	Non-Vacc.Like	I	Excluded
Ohio	16	M	0	28(43)		1(15)	-		I'I	Inconclusive
Tenn.(2)	25	M	1	4(11)			I	Non-Vacc.Like	I, II, III	Inconclusive
Wash.[6]	6	M	4	(37)		(5)	I	Vaccine-Like	I	Excluded

1. The number in parenthesis indicates interval from feeding to onset of paralysis.

2. (NR) California cases not yet officially reported but considered from a special report submitted by the California State Department of Public Health.

3. Considered a "compatible" case if laboratory work in process is not inconsistent with a vaccine relationship.

4. Number in parenthesis following State-designation corresponds with the number of the case in the technical report of the Surgeon General - September 20, 1962.

5. Specimen taken two days after patient received Type II vaccine.

6. Also considered (and listed) with relation to Type III vaccine.

II. Cases Following Type II Vaccine

- No Specimen
0 No Isolate Obtained
** In Process

State	Age	Sex	Doses IPV	Days from Feeding of OPV to Onset of Illness I	II	III	Virus Isolate Type	Character	Antibody Response	Committee Appraisal
Neb	5	F	4	(>90)	16(23)	(>90)	**		Incon.	Inconclusive
Ohio(3)	2	F	2	(85)	(8)	-	III		-	Excluded
Ohio[1]	67	M	0	(64)	(8)	(36)	0		Incon.	Inconclusive

[1] Also considered and listed with relation to Type III vaccine

- No Specimen
0 No Isolate Obtained
** In Process

III. Cases Following Type III Vaccine

State	Age	Sex	Doses IPV	Days from Feeding of OPV to Onset of Illness I	II	III	Virus Isolate Type	Virus Isolate Character	Antibody Response	Committee Appraisal
Mass.	4	M	4	54(64)		26(36)	0		-	Excluded
Mass.	54	F	0			22(24)	0		**	Inconclusive
Mich.(4)	23	M	2 or 4	76(80)		16(20)	III	Intermediate to non-vaccine like	Incon.	Compatible
Mich.(5)	36	F	0			22(28)	III	Vaccine-like	III	Compatible
Neb.(6)	18	F	5	34(42)		7(15)	III	Vaccine-like	Incon.	Compatible
Neb.(7)	51	M	0	51(54)		22(25)	0		Incon.	Compatible
Neb.(8)	37	M	0	43(48)		15(20)	-		Incon.	Compatible
Neb.	50	F	4	61(69)		19(27)	0		I, II, III	Compatible
Neb.	57	M	0	49(57)		12(20)	0		I	Inconclusive
Neb.	6	M	3	49(56)		7(14)	II[1]		Incon.	Inconclusive
Neb.	13	F	3	41(44)		16(19)	III	Vaccine-like	Incon.	Compatible
Neb.	55	M	0	46(52)		10(16)	-		Incon.	Inconclusive
NY(9)	49	M	0	(>90)		26(29)	0		I, II, III	Inconclusive
Ohio[2]	67	M	0	(64)	(8)	(36)	0		Incon.	Inconclusive
Ohio(10)[3]	16	M	0	28(43)		1(15)	-		III	Compatible
Ohio(11)[4]	35	M	0			21(25)	0		I, III	Compatible
Oregon(12)	48	F	0	34(38)		7(11)	III	Vaccine-like	I, II, III	Compatible
Oregon(13)	39	M	0	50(51)		23(24)	III	Vaccine-like	Incon.	Compatible
Oregon(14)	6	M	0	(54)		(27)	I	Non-vaccine like	Incon.	Excluded
							III	Vaccine-like		
Oregon(15)	52	M	0	52(53)		19(20)	III	Vaccine-like	Incon.	Compatible
Penna.	6	M	5	(55)		(8)	III	Vaccine-like	Incon.	Excluded
Wash.(16)[3]	6	M	4	(37)		(5)	I	Vaccine-like	I	Excluded

1 Type II vaccine fed 8 days before specimen collected
2 Also considered (and listed) with relation to Type II vaccine
3 Also considered (and listed) with relation to Type I vaccine
4 Also compatible with Type I household contact spread

Cases Among Household Contacts of Vaccinees

- No Specimen
0 No Isolate Obtained
** In Process

State	Age	Sex	Doses IPV	Days from Feeding of OPV to Onset of Illness I	II	III	Virus Type	Isolate Character	Antibody Response	Committee Appraisal
La.	21	M	0			(26)	I	**	I	Excluded
Mass.	42	F	4	(55)		(25)	-		-	Excluded
Mass.	18/12	M	0	(59)		(18)	I	Intermediate to non-vaccine like	I	Compatible
NY	29	M	0	(55)		(25)	III	Vaccine-like	III	Compatible
Ohio[1]	6/12	M	0	(69)		(33)	III	Vaccine-like	-	Compatible

1 Contact in adjacent apartment

APPENDIX L

SUPPLEMENT TO POLIOMYELITIS SURVEILLANCE REPORT NO. 285

September 30, 1964

ASSOCIATION OF PARALYTIC DISEASE WITH ORAL POLIO VACCINES

I. Press Release

II.* Report of a Special Advisory Committee on Oral Poliomyelitis Vaccine to the Surgeon General of the Public Health Service

III.* Comments on the Report of the Special Advisory Committee By Albert B. Sabin

IV.* Paralytic Disease Associated with Oral Polio Vaccines, By D. A. Henderson, J. J. Witte, L. Morris, and A. D. Langmuir

V. Listing of Reported Cases of Paralytic Poliomyelitis Occurring

Within 30 Days After Receiving the Oral Poliomyelitis Vaccines, 1961-1964

* Appearing in The Journal of the American Medical Association dated October 5, 1964.

HUNTER--WO 2-2125

U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Public Health Service
Washington 25, D. C.

FOR IMMEDIATE RELEASE HEW-C60
Wednesday, September 23, 1964

A special advisory committee to the Surgeon General of the Public Health Service, Department of Health, Education, and Welfare, urged today renewed drives by local communities during the fall and winter to vaccinate the younger age group against poliomyelitis.

The report was prepared by a special advisory committee on oral poliomyelitis vaccine and was made public today by Surgeon General Luther L. Terry.

The committee's report said that the age groups to be immunized and the vaccine chosen for use should be determined locally. The committee said, however, that in its view the oral vaccination of persons over 18 should "generally be recommended only in those situations in which unusual exposure to poliomyelitis might be anticipated, such as epidemics, entry into military service, and travel to other countries."

The committee recommended strongly the immunization of infants during their first year of life and the routine immunization of all children on entering school.

Dr. Terry, in releasing the report, said that the Public Health Service was accepting the committee's recommendations. He pointed out that the shift in emphasis away from adults toward the younger age groups was forecast in a committee report

of December 1962. The advisory committee at that time emphasized the importance of concentrating on the immunization of the younger age groups and noted a "very small risk" incident to the use of oral vaccine in persons 30 years of age and over.

The current committee report also recommends alteration in the sequence of administering monovalent vaccines, with Type II the first to be given. The newly-recommended order is Type II, I, and III.

Dr. Albert Sabin, developer of the oral vaccine and a member of the committee, filed a report dissenting from the committee's recommendations and calling for the continued immunization of all age groups.

The Service is making available the full text of both reports to State Health Officers, professional organizations, and other interested agencies, Dr. Terry said.

The committee's recommendations were based on an exhaustive analysis of 87 reported cases of "polio-like illness associated with the administration of oral vaccines" which have occurred in non-epidemic areas since December 1961.

These cases were considered by the committee on the basis of whether or not they were "compatible with the possibility of having been induced by the vaccine."

I concluded that it is not possible to prove that any individual case was caused by the vaccines and that no laboratory tests available can provide a definitive answer. Nevertheless, the committee said, "Considering the epidemiological evidence developed with respect to the total group of 'compatible' causes, the committee believes that at least some of these cases were caused by the vaccine."

The committee's recommendations were based on an exhaustive analysis of 87 reported cases of "polio-like illness associated with the administration of oral vaccines" which have occurred in non-epidemic areas since December 1961.

These cases were considered by the committee on the basis of whether or not they were "compatible with the possibility of having been induced by the vaccine."

It concluded that it is not possible to prove that any individual case was caused by the vaccines and that no laboratory tests available can provide a definitive answer. Nevertheless, the committee said, "Considering the epidemiological evidence developed with respect to the total group of 'compatible' causes, the committee believes that at least some of these cases were caused by the vaccine."

The extent of the "risk factor", according to the report, is, for Type III, only 1 case in 2.5 million doses administered; for Type I, only 1 in 6 million; and for Type II, only 1 in 50 million.

With respect to the very minimal risk, Dr. Terry emphasized that there should be no apprenhension whatsoever among those who have already taken the oral vaccine.

In its analysis of the 87 cases, the committee found 57 which they considered "compatible."

The "compatible" cases, the report said, occurred largely among adults. Most were widely scattered throughout the country. The onset of illness fell between 4 and 28 days following vaccine administration.

"There was no apparent association of cases with specific lots of vaccine or vaccines produced by a particular manufacturer," the report added.

In urging a renewed effort to vaccinate those still susceptible, most of them poorly-immunized children in economically-depressed population groups, the committee cited the spectacular decline of polio during recent years.

The decline has been from an annual rate of 14.6 cases per 100,000 during 1950-54 to a rate of 1.8 for 1957-61. This represents a decrease of 88 percent.

"On the basis of reports to date, less than 150 cases of paralytic poliomyelitis may be anticipated for the entire year (of 1964)," the report added.

In commenting on this phase of the report, Surgeon General Terry said:

"When you compare this year's record low with the 54,000 cases of polio reported in 1952, the triumph against polio is an historic achievement in preventive medicine. This great victory has been made possible by the work of two

extraordinarily dedicated scientists--Dr. Jonas Salk and Dr. Albert Sabin--and it has come to pass through the devoted efforts of hundreds of organizations and thousands of individuals," Dr. Terry said.

The Surgeon General added: "I heartily and enthusiastically endorse the committee's primary recommendation that every effort be made for the continuing vaccination of infants and younger age groups. Only through this means can we achieve total victory over polio."

Dr. Terry praised the committee for a "painstaking, conscientious and thorough report in the public interest."

Members of the Committee were:

Dr. Ernest A. Ager, State Department of Health, Olympia, Washington

Dr. David Bodian, The John Hopkins University, Baltimore, Maryland

Dr. Gordon C. Brown, University of Michigan School of Public Health, Ann Arbor

Dr. Alice D. Chenoweth, Childrens Bureau, Washington, D.C.

Dr. Geoffrey Edsall, Massachusetts Department of Public Health, Boston

Dr. John P. Fox, Public Health Research Institute of New York, New York

Dr. James L. Goddard, Communicable Disease Center, Public Health Service, Atlanta, Georgia

Dr. A. L. Gray, Mississippi State Board of Health, Jackson

Dr. William McD. Hammon, University of Pittsburgh, Pa.

Dr. Donald A. Henderson, Communicable Disease Center, Public Health Service, Atlanta, Georgia

Dr. David T. Karzon, Childrens Hospital, University of Buffalo, New York, (unable to attend)

Dr. Alexander D. Langmuir, Communicable Disease Center, Public Health Service, Atlanta, Georgia

Dr. Theodore A. Montgomery, California State Department of Public Health, Berkeley

Dr. Roderick Murray, National Institutes of Health, Public Health Service, Betheada, Maryland

Dr. Albert Sabin, The Childrens Hospital Research Foundation, Cincinnati, Ohio

Dr. Edward B. Shaw, University of California School of Medicine, San Francisco

Dr. Paul F. Wehrle, University of Southern California School of Medicine, Los Angeles

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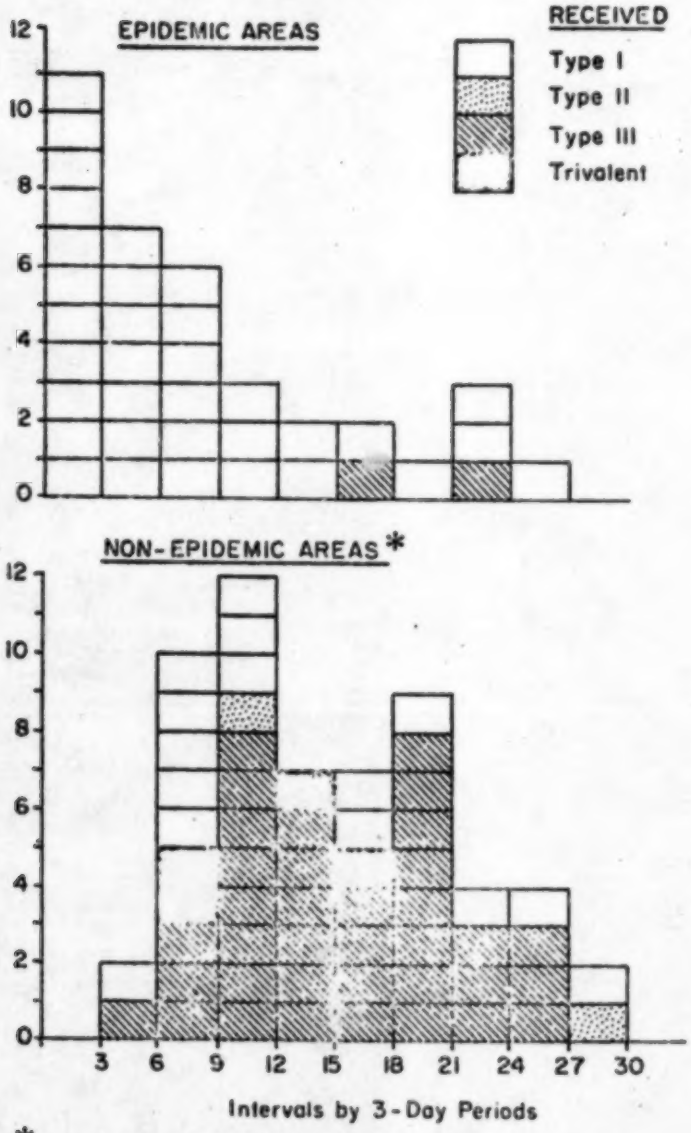
Figure V

PARALYTIC POLIOMYELITIS
OCCURRING WITHIN 30 DAYS OF OPV
INTERVAL BETWEEN VACCINATION AND ONSET
December 1, 1961 through June 27, 1964



*Cases considered compatible by committee

Paralytic Poliomyelitis Cases (Non-Epidemic Areas) With Onsets Less than 30 Days After Receiving OPV

I. Cases Adjudged "Compatible" by Special Advisory Committee

A. Cases Following Type I

	State	County	Age	Sex	Onset	Doses IPV	Type Fed	Interval (Days) OPV to Onset	Isol.	60-Day* Status
1961										
	N. Y.	Chautauqua	23 mo.	F	12-16	4	I	7	-	3
	N. Y.	Chautauqua	56	M	12-28	0	I	28	Neg.	4
1962										
	Calif.	Santa Clara	42	M	10-1	0	I	8	I	4
	Calif.	Alameda	32	M	10-1	0	I	7	I	3
	Calif.	San Francisco	2	F	10-11	2	I	18	I	3
	Calif.	Santa Clara	58	M	10-18	0	I	25	I	3
	Calif.	San Mateo	7	F	10-24	6	I	22	II**	2
	Calif.	San Diego	35	M	11-6	0	I	9	I	3
	Ill.	Stephenson	16	M	10-4	Unk	I	4	I	3
	Iowa	Story	14	F	10-14	3	I	9	I	3
	Tenn.	Gibson	25	M	8-30	1	I	10	I	3
1963										
	Wash.	Yakima	61	F	3-14	0	I	11	I	2
	Wisc.	Chippewa	18	M	3-26	Unk	I	10	I	3
1964										
	Ga.	Bartow	15	M	3-5	5	I	25	Neg.	3
	Md.	Pr. Georges	15	M	5-9	0	I	20	I	3

B. Cases Following Type II

1962										
	Ariz.	Maricopa	6	M	3-9	3	II	12	-	3
1964										
	N. C.	Lenoir	49	M	6-14	0	II	28	-	

C. Cases Following Type III

	State	County	Age	Sex	Onset	Doses IPV	Type Fed	Interval (Days) OPV to Onset	Isol.	60-Day* Status
1962										
	Mich.	Branch	23	M	7-15	4 (2)	III	16	III	3
	Mich.	Midland	36	F	7-20	0	III	22	III	3
	Neb.	Douglas	18	F	7-1	5	III	7	III	3
	Neb.	Douglas	51	M	7-16	0	III	22	Neg.	3
	Neb.	Dodge	37	M	7-23	0	III	15	-	3
	Neb.	Lancaster	6	M	8-5 or 8-12	3	III	7 or 14	II***	3
	Neb.	Cherry	55	M	8-15	0	III	10	-	3
	Neb.	Phelps	50	F	8-16	4	III	19	Neg.	3
	Neb.	Lincoln	57	M	8-24	0	III	19	Neg.	4
	Neb.	Keya Paha	13	F	9-3	3	III	16	III	3
	Ohio	Portage	16	M	6-8	0	III	15	Neg.	3
	Ohio	Cuyahoga	36	M	7-18	0	III	24	Neg.	4
	Okla.	Logan	33	M	8-7	0	III	17	Neg.	3
	Oreg.	Washington	48	F	5-5	0	III	7	III	4
	Oreg.	Benton	52	M	6-26	0	III	19	III	4
1963										
	Calif.	Sacramento	39	M	1-24	0	III	11	III	4
	Calif.	Los Angeles	30	M	3-1	0	III	20	Neg.	4
	Calif.	Napa	39	M	3-23	5	III	13	III	2
	Calif.	Shasta	1 1/2	M	3-26	3	III	16	III	3
	Calif.	Los Angeles	27	M	12-10	5 or 6	III	20	III	3
	Mass.	Middlesex	21	M	5-28	Unk	III	8	III	2
	Mass.	Middlesex	27	F	6-7	4	III	19	III	3
	Minn.	hennepin	19	M	5-27	0	III	14	Neg.	3
	Pa.	Schuykill	30	M	6-8	0	III	14	Neg.	3
	Pa.	Delaware	39	M	11-21	0	III	25	-	5
	Pa.	Delaware	47	M	11-21	0	III	25	Neg.	3
	S. C.	Spartanburg	3	M	12-18	0	III	10	III	3
	Tenn.	Montgomery	11 mo.	M	6-16	0	III	10	III	3
	Texas	Bexar	20	M	1-25	0	III	12	III	2
	Idaho(NOR)		39	M	4-12	Unk	III	26	III	4
	Utah(NOR)	Sevier	4	M	c.4-30	4	III	c.9	III	4

APPENDIX M

ORAL VACCINE: ASSOCIATED PARALYTIC POLIOMYELITIS, 1962

Henry M. Gelfand, MD, Atlanta

UNTIL RECENTLY, there was almost universal agreement that living attenuated, oral poliovirus vaccine (OPV) composed of the Sabin strains is safe, both to the primary vaccinee and to his contacts. This reputation for safety was won on the basis of the use of OPV in millions of persons in the US and many other countries. Although the thoroughness of routine reporting of morbidity and of special surveillance for possible vaccine-induced cases of paralytic poliomyelitis differed greatly among the various programs, no evidence had been adduced to show that this vaccine, composed of these strains, had ever caused the disease it was designed to prevent.

From July through November, 1962, a small number of cases which had followed the use of oral vaccine came to light and they have cast some doubt on the safety of OPV in adult vaccinees. This cluster of cases was intensively studied and discussed in a series of meetings by a Special Advisory Committee on Oral Poliomyelitis Vaccine to the Surgeon General, USPHS. This Committee concluded in its report of September 20,[1] that "...there is sufficient epidemiological evidence to indicate that at least some of these cases have been caused by the type III vaccines." After considering new case reports accumulated during the following few months, and additional laboratory data, in its report of Dec 18,[2] the Committee recommended:

Chief, Enterovirus Unit, Communicable Disease Center, USPHS, Department of HEW.

Based on a presentation at the Annual Meeting of the Association of Teachers of Preventive Medicine, Miami, Fla., Oct 14, 1962.

"...(1) that community plans for immunization be encouraged, using all three types; and, (2) that immunization be emphasized for children in whom the danger of naturally occurring poliomyelitis is greatest and who serve as the natural source of poliomyelitis infection in the community. Because the need for immunization diminishes with advancing age and because potential risks of vaccine are believed by some to exist in adults, especially above the age of 30, vaccination should be used for adults only with the full recognition of its very small risk. Vaccination is especially recommended for those adults who are at higher risk of naturally occurring disease; for example, parents of young children, pregnant women, persons in epidemic situations and those planning foreign travel.

Of greatest importance is the continuing vaccination of oncoming generations."

It is the purpose of the present communication to review the data upon which this conclusion was based and to discuss some theoretical problems in analysis and evaluation of the signifi-

cance of OPV-associated paralytic poliomyelitis. Only cases accepted as "compatible with the possibility of having been induced by the vaccine" and included in the two reports just cited will be considered in this article. A summary of some pertinent details relating to these cases is presented in Table 1. Other cases of paralytic poliomyelitis followed the use of OPV in 1962 and were considered by the Committee. A majority of the Committee believed these to be clearly incompatible with the possibility of vaccine induction or as "inconclusive" - on clinical, epidemiologic, or laboratory grounds. Still other cases which had followed the use of OPV were not considered to be part of this investigation, because they had occurred in epidemic settings where vaccine had been used as a control measure. Under those circumstances, new cases are expected for several weeks after vaccination.

The compilation of the data in Table 1 was made possible by the work of hundreds of practicing physicians and others in the epidemiology and laboratory divisions of the various state health departments and of the Communicable Disease Center of the Public Health Service. The Surgeon General has gratefully acknowledged their contri-. . . [c]ommunity, all three types were in extensive use at about the same time, if the country is considered as a whole. The predominant association of "compatible" cases with Type 3 OPV is apparent.

Other Laboratory Data. - The difficulties and limitations of characterization of poliovirus strains as a tool for the solution of problems of OPV-case association have been discussed. All that can be said is that those patients from whom "vaccine-like" virus strains were isolated were almost certainly excreting the progeny of vaccine viruses.

Unfortunately, no naturally occurring poliovirus strains of the same type were available from the same localities for comparative tests. However, only rarely are "vaccine-like" strains found where OPV has not been used.[22] In those few instances in which monkey intracerebral tests were performed, the results confirmed that the fecally excreted viruses were attenuated. Neither antigenic nor virulence tests added appreciably to epidemiologic analysis.

The most useful application of antigenic strain differentiation would be in the testing of a virus isolate obtained from tissues from a fatal case. The recovery of a "vaccine-like" strain from the brain or spinal cord would be almost certain evidence for incriminating the vaccine as the causative agent, even if all other evidence were equivocal. Since there have been no fatal cases in the aggregate under investigation in

1962, no CNS strains have been available for testing.

The inclusion of each case in a problem group must be predicted on the failure to detect concurrent infection with another potentially paralytogenic agent. As already mentioned, no nonpoliovirus infection was demonstrated, by isolation of virus or serologic change, in any single case included in the present investigation. However, it must be remembered that the finding of random infections with other enteroviruses might be mere coincidence in the opposite direction. Each instance of dual infection would have to be considered in the light of our present incomplete knowledge. Greater understanding will develop with accumulating experience.

Comment and Summary

We expected and we have found that cases of paralytic poliomyelitis occur in

temporal relationship with the widespread use of OPV, particularly if it is used during the summer season. It is the responsibility of the appropriate authorities to establish and maintain poliomyelitis surveillance of a very high standard and to examine reports of vaccine-associated disease critically and objectively, making maximum use of all available clinical, laboratory, and epidemiologic data. The Poliomyelitis Surveillance Unit of the Communicable Disease Center, with its long history of experience in this field, performed this task in the US in 1962 with extraordinary skill and speed. However, it was hampered in some instances by delays in reporting by the patients themselves, attending physicians, hospitals, and local public health agencies.

After close examination, it was possible to eliminate many cases from serious consideration of a causal rela-

tion to vaccine on the basis of incorrect or uncertain diagnosis, the recovery of a poliovirus not fed as vaccine, too long or too short an interval between vaccination and the disease onset, or some other factor. There was then left a residuum of suspicious cases.

Such a collection of cases was hard to evaluate. They had been diagnosed clinically as "poliomyelitis," they had occurred after use of OPV at an interval compatible with the incubation period, and the only demonstrable infection was with a poliovirus of the type fed as vaccine. This triad of circumstances constituted the basis for considering them "compatible with vaccine-induced disease." Occurring, as they did, in a rather random and sporadic manner, they might have remained only a suspicion and a puzzle if the aggregation of cases had not presented certain epidemiologic features that appeared significant.

There were three characteristics of this group of cases that appeared most meaningful to the Surgeon General's Special Advisory Committee on Oral Poliomyelitis Vaccine: the adult age distribution of "compatible" cases, the frequent interval of one to four weeks between vaccination and onset of symptoms, and the predominance of cases after use of Type 3 OPV as compared with Types 1 and 2. Although it remained impossible to decide whether or not an individual case had been caused by the oral vaccine, this constellation of findings suggested that, as a group, at least some of these cases had been causally related to OPV. Because of the widespread interest in possible vaccine-associated cases in the US, in 1962, and the zealous activities of the Poliomyelitis Surveillance Unit, it is unlikely that any significant number of suspicious cases went unreported. Since it can be concluded only that

at least some of the "compatible" cases were one case per 4.4, 0, and 1.4 million "attack rates" express the maximum potential risk associated with the use of these vaccines; the actual risk may be considerably less. These rates were one case per 4.4, 0, and 1.4 million vaccines for OPV Types 1, 2, and 3, respectively. Since a complete course of OPV consists of the administration of all 3 types, these rates must be added to produce a "combined maximum potential risk" of one case per 1.04 million complete immunizations.

The combined maximum potential risk, moreover, was not felt equally by all age groups; in 12 of the 18 "compatible" cases the patients were more than 30 years of age. With only one "com-. . .

APPENDIX N

Boise, Idaho

June 26, 1964

Air Mail

Pierce Gardner, M.D.
Assistant Chief
Poliomyelitis Surveillance Unit
Communicable Disease Center
Atlanta, Georgia 30333

DAVIS, Glynn

Dear Doctor Gardner:

Mr. Glynn Davis developed a paralytic illness within a thirty-day period following the administration of Type III oral poliomyelitis vaccine. He may have had one or two injections of poliomyelitis vaccine (Salk) in prior years. Dates of vaccination and illness are as follows:

Oral poliomyelitis vaccine --	
Type I	February 3, 1963
Type III	March 17, 1963
Onset of illness	April 12, 1963
Onset of paralysis	April 14, 1963

Hospitalized at Ashton Memorial Hospital	April 17, 1963
Transferred to Idaho Falls LDS Hospital	April 24, 1963
Transferred to Elks Convalescent Center, Boise	May 14, 1963
Transferred to VA Hospital, Boise	June 13, 1963

Enclosed are hospital and physician examinations at the time of admission of Mr. Davis to the Idaho Falls LDS Hospital on April 24, 1963, and a consultation after his transfer to Boise. Doctors John S. McMillan and Maurice M. Burkholder practice the specialty of internal medicine.

Spinal fluid tests are as follows:

	During hospitalization at Ashton	April 24, 1963
Pressure	165mm	96mm
Jugular pressure	---	254mm, rapid fall to 136
WBC	60	78
Polys	64%	3%

Sugar	--	66 mgs %
Protein	--	40 mgs %
Pandy	Pos	--
Wasserman	--	Neg.

Mr. Davis was released from the Veterans Administration Hospital in the early fall of 1963 and has continued with physiotherapy treatment at the Veterans Administration Hospital on an outpatient basis until the present time. Physiotherapy will be discontinued during the week of June 29, 1964, and muscle evaluations at time of admission and during the week of June 29, 1964, will be obtained and forwarded. His diagnosis at the Veterans Administration Hospital is paralytic poliomyelitis (old definition of "inflammation of grey matter of spinal cord") etiology undetermined.

The paralysis of the right triceps has disappeared. The present involvement is limited to below the knees with

weakness of the anterior muscle group of the right lower leg and both anterior and posterior muscle groups of the left leg. He continued to show improvement of muscle function and apparent return of muscle use from a flaccid paralysis state. He now walks with a left leg brace, elastic aid to prevent foot drop on the right, and crutches.

There are unusual circumstances concerning the clinical course and the inconclusive laboratory findings in this case. A flu like illness may have been present among residents of West Yellowstone as noted by Mr. Davis. There were sensory changes found by one consultant. There has been an apparent recovery of partial muscle function over an extended period of time. The etiology of this case of paralysis has not been determined and a large number of virus deseases are to be considered. The present diagnosis of

lower neuron disease with paralysis -- etiology unknown -- is the continuing diagnosis by this office of this interesting case.

Sincerely yours,

PREVENTIVE MEDICINE
DIVISION

John A. Mather, M.D.
Director

Enclosures

APPENDIX O

43 C.F.R. § 73.114(b)(1)(iii) provides:

(iii) DETERMINATION OF NEUROVIRULENCE. At the conclusion of the observation period comparative histopathological examinations shall be made of the lumbar cord, cervical cord, lower medulla, upper medulla and mesencaphalon of each monkey in the groups injected with virus under test and those injected with the NIH Reference Attenuated Poliovirus, except that for animals dying during the test period, these examinations shall be made immediately after death. The animals shall be examined to ascertain whether the distribution and histological nature of the lesions are characteristic of poliovirus infection. A comparative evaluation shall be made of the evidence of neurovirulence of the virus under test and the NIH Reference Attenuated Poliovirus with respect to (a) the number of animals showing lesions characteristic of poliovirus infection, (b) the number of animals

showing lesions other than those characteristic of poliovirus infection, (c) the severity of the lesions, (d) the degree of dissemination of the lesions, and (e) the rate of occurrence of paralysis not attributable to the mechanical injury resulting from inoculation trauma. The virus pool under test is satisfactory for poliovirus vaccine manufacture only if at least 80 percent of the animals in each group survive the observation period and if a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the NIH Reference Attenuated Poliovirus.

The "NIH Reference Attenuated Poliovirus" was designated by regulation to be Type I poliovirus. 42 C.F.R. § 73.111. It was referred to herein as the "reference strain."

The regulation specifically refers to "virus pool" under test. Both the district

court and the briefs filed with this court treat "virus pool" and "lots" interchangeably. We continue this treatment.

43 C.F.R. § 73.114(b)(1)(iii) is a regulation promulgated by the Surgeon General pursuant to the Public Health Service Act, 43 U.S.C. § 201 et seq.; see 43 U.S.C. § 262(d).

Opposition

Office - Supreme Court, U.S.
FILED
JAN 5 1982
ALEXANDER L. STEVAS,
CLERK

No. 81-644

In the Supreme Court of the United States

OCTOBER TERM, 1981

GLYNN RICHARD DAVIS, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

REX E. LEE
Solicitor General
Department of Justice
Washington, D.C. 20530
(202) 633-2217

TABLE OF AUTHORITIES

Page

Cases:

Rahn v. *United States*, 222 F. Supp. 775 6

Spevack v. *United States*, 390 F. 2d 977 6

Toal v. *United States*, 438 F. 2d 222 6

United States v. *Kubrick*, 444 U.S. 111 ..... 2, 3-4, 5

Statute:

Federal Tort Claims Act, 28 U.S.C. 2401(b) 1, 2

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GLYNN RICHARD DAVIS, PETITIONER

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UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

---

1. The question presented in this case is whether petitioner's claim under the Federal Tort Claims Act is barred by the applicable two-year statute of limitations, 28 U.S.C. 2401(b). Petitioner filed his administrative claim in 1973 seeking damages for injuries he suffered in 1963, allegedly as a result of the government's negligence in its administration of a nationwide program for mass immunization against poliomyelitis, using the Sabin oral vaccine (Pet. App. A-1 to A-4).

The vaccine was licensed and tested by the Division of Biological Standards (DBS), a part of the Department of Health, Education, and Welfare, and it was administered at state and local immunization centers (Pet. App. A-1 to A-2). Petitioner was administered Type III Sabin vaccine at an immunization center in March 1963; within 30 days he was paralyzed from the waist down and manifested other

symptoms of polio (*id.* at A-2). In 1964, petitioner brought suit against Wyeth Laboratories, Inc., manufacturer of the vaccine he had ingested (*ibid.*).[1]

In 1965, during the course of that litigation, Wyeth noticed the deposition of Dr. Ruth Kirschstein, the chief of the pathology section of Viral Immunology, DBS, accompanied by a subpoena duces tecum ordering her to bring to the deposition all records relating to the DBS testing of vaccine Lot No. 03503. The vaccine petitioner ingested was from this lot. Dr. Kirschstein brought records documenting one neurovirulence test on the lot which indicated that the results fell within acceptable limits (Pet. App. A-2 to A-3). Petitioner alleges that not until 1973 did he learn, from an attorney engaged in another lawsuit, that a second neurovirulence test had been performed on Lot No. 03503 and that the results of that test exceeded acceptable limits (*id.* at A-4).

Petitioner filed an administrative claim under the Tort Claims Act in April 1973 and brought this action in the United States District Court for the District of Idaho in April 1974 (Pet. App. A-4). The district court granted the government's motion for summary judgment, ruling that the action was barred by the applicable two-year statute of limitations, 28 U.S.C. 2401(b) (Pet. App. A-22 to A-24).

The court of appeals affirmed, with one judge dissenting (Pet. App. A-1 to A-18). The court concluded that petitioner's claim had accrued in April 1963 and that it therefore was time-barred. Relying on *United States* v. *Kubrick*, 444 U.S. 111 (1979), the court reasoned (Pet. App. A-11; footnote omitted):

---

[1]In that action the district court ruled in favor of the manufacturer, but the court of appeals reversed and remanded. *Davis* v. *Wyeth Laboratories, Inc.*, 399 F. 2d 121 (9th Cir. 1968). The case was settled by the parties prior to a second trial (Pet. App. A-2 n.1).

> [Petitioner] was aware in April, 1963, that he had been injured and that the Sabin vaccine was the likely cause of his injury. With knowledge of the fact of injury and its cause, [petitioner] was at the time of his injury placed on the same footing as other negligence plaintiffs.

The court of appeals rejected petitioner's contention that the limitations period was tolled by the government's alleged fraudulent concealment of the results of the second neurovirulence test during the October 1965 deposition of Dr. Kirschstein.[2] The court noted (*id.* at A-12) that the allegation was irrelevant because, by that time, the two-year period for filing the tort claim had already expired. As to the government's conduct *during* that two-year period, the court acknowledged that the government might have been negligent in its publication of reports on the vaccine, but it held that the government's failure "to ascertain and publish the fact of its negligence" did not amount to fraudulent concealment (*ibid.*).

2. The decision of the court of appeals is correct and does not conflict with decisions of this Court or of other courts of appeals. Both lower courts held that petitioner's claim for injuries sustained in 1963 was barred by the statute of limitations. Further review of this fact-bound question is unwarranted.

a. Contrary to petitioner's contention (Pet. 25-35), the decision below is entirely consistent with *United States* v. *Kubrick*, *supra*. As the Court noted in *Kubrick*, the general rule is that a claim under the Federal Tort Claims Act "accrues at the time of the plaintiff's injury." 444 U.S. at

---

[2]The appendix to the petition contains a typographical error: the court of appeals referred to the October 1965 deposition, not to the "October, *1975*, deposition" (Pet. App. A-12; emphasis added). See 642 F. 2d 328, 331.

120. A number of courts have held that in medical malpractice cases, in which the injury may not manifest itself until long after it has been inflicted, the claim should be deemed to accrue only later, when the victim discovers both the injury and its cause. *Id.* at 120-121 & n.7. *Kubrick* rejected any extension of this "discovery" rule, however, and it thus reversed a decision extending the accrual period until the plaintiff became aware, not only of his injury and its cause, but also of the fact that his injury had been negligently inflicted. *Id.* at 123.

Even assuming that the "discovery" rule applies to this case, the court of appeals correctly held that petitioner's claim was time-barred. Petitioner contracted polio in April 1963, not long after he was given the vaccine; and according to his own affidavit (Pet. App. A-32 to A-33; emphasis in original), he "began an intensive search in approximately *June*, 1963, to determine why I was given a vaccine that would give me the disease instead of preventing it." Petitioner does not contend that the government's involvement in the vaccine program—in particular its responsibility for testing the lots of vaccine—was unknown to him at that time. Hence, like any victim with a potential claim for negligent injury, he knew that he had been injured, he knew (or at least had strong reason to suspect; see Pet. 28) the cause of the injury (the vaccine), and he knew the identity of those with responsibilities respecting the causative agent (the government and the vaccine manufacturer, Wyeth Laboratories, Inc.). He was, in fact, sufficiently sure of the connection between the vaccine and his injury to bring suit against Wyeth in 1964 for, *inter alia*, negligent manufacture of the vaccine and breach of an implied warranty that the vaccine was fit for use (see *Davis* v. *Wyeth Laboratories, Inc.*, 399 F. 2d 121, 125 (9th Cir. 1968)).

Kubrick does not, as petitioner contends, warrant extending the accrual time for his claim against the government

until he became aware of test results that would support an allegation that Lot No. 03503—the lot of vaccine from which the dose administered to him came—was negligently approved for use by the government. *Kubrick* held only that a malpractice claim accrues when the victim knows the existence of his injury and its cause; it does not suggest that the limitations period begins to run only after the claimant has accumulated proof of the precise manner in which the injury was inflicted and the way in which the mechanism relates to the possible negligence of the potential defendant.[3]

b. There is similarly no merit to petitioner's argument (Pet. 35-42) that the limitations period was tolled by fraudulent concealment. As the court of appeals correctly concluded, the period had run before October 1965, when the alleged act of fraudulent concealment occurred in connection with Dr. Kirchstein's deposition in the suit against Wyeth.

Petitioner's reliance on government reports respecting the mass immunization program is also misplaced. The September 1962 report stated (Pet. App. A-76) that some of the 11 polio cases following the administration of Type III Sabin vaccine (the type administered to petitioner) might have been caused by the vaccine. The December 1962 report stated (*id.* at A-87) that, while the committee issuing the report did not think that any individual polio case could be "proved to be caused by the vaccine," because no "definitive" answer had been supplied by any laboratory test, the committee nonetheless concluded that some of the cases it

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[3]Under petitioner's theory, the limitations period for suits arising out of airplane crashes could be extended indefinitely, and would not begin to run until after the claimant had assembled evidence of pilot error, negligent maintenance, negligent manufacture, and the like. Such a theory essentially negates the whole purpose of a statute of limitations. See *United States* v. *Kubrick*, *supra*, 444 U.S. at 125.

had studied were " 'compatible' with the possibility of having been induced by the vaccine." The court of appeals correctly held (Pet. App. A-12) that the limited findings in these reports, while perhaps indicating that "the government was negligent in maintaining and publishing records," did not amount to fraudulent concealment. Indeed, as the court noted (*id.* at A-12 n.10), the reports served as "additional notice to [petitioner] of the government's involvement in his claim." Accordingly, it properly held that there was no ground for extending the period for accrual of petitioner's claim.[4]

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

REX E. LEE
Solicitor General

JANUARY 1982

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[4]The "concealment" cases on which petitioner relies (Pet. 37-38) are inapposite. In *Toal* v. *United States*, 438 F. 2d 222 (2d Cir. 1971), and *Rahn* v. *United States*, 222 F. Supp. 775 (S.D. Ga. 1963), the courts merely held that the plaintiffs' malpractice claims accrued when they first learned that they had suffered injuries from medical treatment and did not merely suffer from the effects of the accidents that caused them to seek treatment in the first place. If petitioner had been led to the reasonable belief that there was no connection between the vaccine and his disease, those cases might be pertinent. In *Spevack* v. *United States*, 390 F. 2d 977 (Ct. Cl. 1968), the court held only that a claim for improper use of a trade secret did not accrue until the plaintiff was on notice that the government had actually used it.

Petitioner's Reply Brief

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

G.D. SEARLE & COMPANY,

Petitioner,

vs.

SUSAN COHN and WALTER COHN,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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TABLE OF CONTENTS

		Page
TABLE OF AUTHORITIES		ii
I.	The New Jersey Tolling Statute Imposes An Undue, Discriminatory, And Impermissible Burden On Interstate Commerce	1
	A. *Per Se* Invalidity	2
	B. Impermissible Discrimination And Excessive Burden	6
II.	The Only Way Unregistered Foreign Corporations Can Obtain The Benefit Of The Statute Of Limitations Is To Submit To A Licensing Scheme And Generally Consent To Suit In New Jersey	8
	A. Submission To A Licensing Scheme Is The Only Way Of Registering An Agent In New Jersey	9
	B. In Any Event, New Jersey Law Improperly Conditions The Availability Of The Statute Of Limitations On A Corporation's General Consent To Suit In The State	11
CONCLUSION		13

TABLE OF AUTHORITIES

CASES

	Page
Adam v. *Saenger*, 303 U.S. 59 (1938)	11
Allenberg Cotton Co. v. *Pittman*, 419 U.S. 20 (1974)	2, 3, 5, 9
Davis v. *Farmers' Co-operative Equity Co.*, 262 U.S. 312 (1923)	11
Eli Lilly & Co. v. *Sav-On-Drugs*, 366 U.S. 276 (1961)	2
Exxon Corp. v. *Governor of Maryland*, 437 U.S. 117 (1978)	4
Great Atlantic & Pacific Tea Co. v. *Cottrell*, 424 U.S. 366 (1976)	6
Grow Farms Corp. v. *National State Bank*, 167 N.J. Super. 102, 400 A.2d 535 (1979)	5
Hughes v. *Oklahoma*, 441 U.S. 322 (1979)	6, 7
Hunt v. *Washington Apple Advertising Comm'n*, 432 U.S. 333 (1977)	4, 6, 7
International Shoe Co. v. *Washington*, 326 U.S. 310 (1945)	9, 11
International Text-book v. *Pigg*, 217 U.S. 91 (1910)	3
Lewis v. *BT Investment Managers, Inc.*, 447 U.S. 27 (1980)	6, 7
Litton Industrial Systems, Inc. v. *Kennedy Van Saun Corp.*, 117 N.J. Super. 52, 283 A.2d 551 (Law Div. 1971)	11, 12
National Equipment Rental, Ltd. v. *Szukhent*, 375 U.S. 311 (1964)	11

	Page
Neirbo Co. v. *Bethlehem Shipbuilding Corp., Ltd.*, 308 U.S. 165 (1939)	11
Pennsylvania Fire Ins. Co. v. *Gold Issue Mining Co.*, 243 U.S. 93 (1917)	11
Philadelphia v. *New Jersey*, 437 U.S. 617 (1978)	8
Pike v. *Bruce Church, Inc.*, 397 U.S. 137 (1970)	2, 8
Scanapico v. *Richmond, F.&P. R.R. Co.*, 439 F.2d 17 (2d Cir. 1970)(en banc)	11
Shaffer v. *Heitner*, 433 U.S. 186 (1977)	8
Sioux Remedy Co. v. *Cope*, 235 U.S. 197 (1914)	2, 3
United States v. *Kubrick*, 444 U.S. 111 (1979)	4
Velmohos v. *Maren Engineering Corp.*, 83 N.J. 282, 416 A.2d 372 (1980)	9, 10
Western & Southern Life Insurance Co. v. *State Board of Equalization*, ___ U.S. ___, 49 U.S.L.W. 4542 (May 26, 1981)	3
World-Wide Volkswagen Corp. v. *Woodson*, 444 U.S. 286 (1980)	5

MISCELLANEOUS

New Jersey Ct. R. 4: 4-4(c)	9
New Jersey Statutes Annotated, 14A:4-1	3
14A:4-5	3
14A:13-1 *et seq.*	9
14A:13-2	3
54: 10A-2	3